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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/664,490	Confirmation #4845
Applicant	:	John F. Boylan et al.	
Filed	:	September 17, 2003	
Title	:	EMBOLIC PROTECTION DEVICES	
Art Unit	:	3731	
Examiner	:	Michael G. Mendoza	
Docket No.:	:	ACSES-65471 (G1738USD2)	
Customer No.		24201	April 18, 2008

MAIL STOP APPEAL BRIEF-PATENTS

PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention is directed towards a filtering device for capturing embolic debris in a blood vessel created during the performance of a therapeutic interventional procedure, such as a balloon angioplasty or stenting procedure, in order to prevent the embolic debris from blocking blood vessels downstream from the interventional site. The device of the present invention is particularly useful when performing an interventional procedure in critical arteries, such as the carotid arteries, in which vital downstream blood vessels can easily become blocked with embolic debris, including the main blood vessels leading to the brain. When used in carotid procedures, the present invention minimizes the potential for a stroke occurring during the procedure. As a result, the present invention provides the physician with a higher degree of confidence

that embolic debris is being properly collected and removed from the patient's vasculature during the interventional procedure.

The presently claimed invention includes a shaft member having a distal end, a proximal end and a stop fitting. A filtering assembly is rotatably mounted on the shaft member near the distal end of the shaft. The filtering assembly includes an expandable strut assembly and a filter attached to the strut assembly for capturing embolic debris, the filtering assembly being mounted on an outer tubular member which is coaxially disposed over an inner tubular member having a length shorter than the outer tubular member. One end of the inner tubular member is adapted to abut against the stop fitting located on the shaft member for limiting axial movement of the filtering assembly along the shaft member.

NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of October 18, 2007 is being filed concurrently herewith along with the appropriate fee.

ISSUES ON APPEAL

At issue is whether claims 1-4 were incorrectly rejected under 35 U.S.C. 102 (e) as being anticipated by U.S. Patent No. 6,461,370 to Gray et al. (the "Gray patent").

At issue is whether claim 5 was incorrectly rejected under 35 U.S.C. § 103(a) as being obvious in view of the Gray patent.

A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. A copy of the final Office Action dated October 18, 2007 is attached hereto as Exhibit C. A copy of the Gray patent is attached as Exhibit D.

ARGUMENTS

Rejection of claims 1-4 as being anticipated by the Gray patent

Appellant strongly disagrees with the Examiner's interpretation of the Gray patent. The Gray patent shows a filtering assembly including an expandable strut assembly made from an outer braid **56** coaxially disposed over an inner braid inner **54**. These inner and outer braids **54, 56** collapse and expand a filter mesh **58** (the filter) and act as the mechanism for deploying and collapsing the filter mesh **58**. Collectively, these inner and outer braids **54, 56** and mesh **58** form the filtering assembly. Claim 1 specifically recites that the filtering assembly is **rotatably** mounted on the shaft member near its distal end. However, the filtering assembly of the Gray patent is not rotatably mounted to the core wire **34** (the shaft member) as recited in claim 1. Rather, the distal end **57** of the inner and outer braids **54, 56** are fixedly attached to the core wire and thus cannot possible rotate on the core wire **34**. Appellant relies on column 6, lines 56-63 of the Gray patent which reads as follows:

> The filter may then be deployed by actuating an actuating mechanism (not shown) coupled to the core wire 34 for axially moving the shaft 38 relative to the core wire. As the shaft advances axially along the core wire in the distal direction, the filter basket 52, **having its distal end 57 attached to the fixed core wire and its proximal end connected to the shaft**, compresses axially and expands radially outwardly against the inner walls of the blood vessel. [Emphasis added]

Therefore, while the tubular shaft **38** and proximal end of the filtering assembly may **slide** along the core wire **34** to open and close the filter **58**, the filtering assembly is unable to rotate about the core wire **34** since the distal end **57** is attached to the core wire **34**. There is no disclosure in the Gray patent that the distal end **57** is, or may be, rotatably attached to the core wire **34**. Accordingly, the Gray patent fails to disclose a filtering assembly that is rotatably mounted to a shaft member. Appellant submits that claim 1 is not anticipated by the Gray patent.

The Examiner has apparently interpreted this tubular shaft **38** as the outer tubular member recited in the pending claims. Additionally, the Examiner has apparently

interpreted the coiled spring **46** as the inner tubular member. Claim 2 further calls for the shaft member to be a guide wire with a distal spring tip, the distal spring tip serving as a stop fitting which **abuts against the inner tubular member**. Appellant submits that this structure is also lacking in the Gray patent. The Gray patent does show a distal spring tip **66** attached to the end of the core wire **34**. However, the coil spring **46** (which the Examiner considers to be the inner tubular member) simply does not abut against this distal spring **66** as required in claim 2. Figure 3 of the Gray patent shows the filter assembly in its collapsed position and Figure 4 show the filter assembly in its **fully opened position**. The filter assembly does not extend beyond the position shown in Figure 4. It is clear that the inner member (coil spring **46**) does not abut the distal spring **66** in any manner during usage. Accordingly, the specific structure recited in claim 2 is not found in the Gray patent as well.

Claim 3 further states that each of the inner and outer tubular members has a proximal end and a distal end and the guide wire includes a second stop fitting in an abutting relationship with the **proximal ends** of the outer and inner tubular members. Again, the Examiner has interpreted the tubular shaft **38** as the outer tubular member and the spring **46** as the inner member. The Gray patent does not disclose the structure recited in claim 3, namely, a second stop fitting in an abutting relationship with the **proximal ends** of the outer and inner tubular members. Moreover, the Examiner has not indicated where such a structure can be found in the Gray patent. Accordingly, the Gray patent does not anticipate claim 3.

Claim 4 further requires the outer tubular member to extend over a portion of the spring tip coil of the guide wire. The tubular shaft **38** of the Gray device does not extend over the distal spring tip coil **66** of the core wire **34** in either the collapsed position, as shown in Figure 3, or the full expanded position, as shown in Figure 4. Reference is made with respect to Appellant's position above regarding the positioning of the filter assembly from its collapsed position and its fully expanded position. As can be clearly seen in the drawings of the Gray patent, no portion of the outer member **38** extends over

the distal spring **66 at any time** during usage. Appellant submits that the Gray patent does not anticipate claim 4.

For at least these reasons alone, the Gray patent fails to disclose the basic elements recited in claims 1-4. Accordingly, Appellant respectfully submits that the Examiner has incorrectly rejected claims 1-4 based on the Gray patent.

Rejection of Claim 5 under 35 U.S.C. 103 (a) over the Gray patent

Claim 5 is dependent on claim 2. As stated above, the Gray patent lacks the basic elements recited in claims 1 and 2. Therefore, Appellant submits that the claimed invention of claim 5 would not be obvious over the Gray patent. Appellant respectfully points out that the Examiner has incorrectly rejected claim 5 based on the Gray patent.

The Notice of Appeal filing fee of $510, as well as, the Pre-Appeal Brief fee of $510 is being paid by credit card with this electronic transmission. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,
FULWIDER PATTON LLP

By: /Thomas H. Majcher/
Thomas H. Majcher, Reg. No. 31,119

213464.1

EXHIBIT A

LISTING OF CLAIMS:

1. (Previously Presented) An embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising:

a shaft member having a distal end, a proximal end and a stop fitting; and

a filtering assembly rotatably mounted on the shaft member near the distal end thereof, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly for capturing embolic debris, the filtering assembly being mounted on an outer tubular member which is coaxially disposed over an inner tubular member having a length shorter than the outer tubular member, wherein one end of the inner tubular member is adapted to abut against the stop fitting located on the shaft member for limiting axial movement of the filtering assembly along the shaft member.

2. (Original) The embolic protection device of claim 1, wherein:

the shaft member is a guide wire and includes a distal spring tip coil, the spring tip coil serving as the stop fitting which abuts against the inner tubular member.

3. (Previously Presented) The embolic protection device of claim 2, wherein:

each of the inner and outer tubular members has a proximal end and a distal end and the guide wire includes a second stop fitting in an abutting relationship with the proximal ends of the outer and inner tubular members.

4. (Original) The embolic protection device of claim 2, wherein:

the outer tubular member extends over a portion of the spring tip coil of the guide wire.

5. (Original) The embolic protection device of claim 2, wherein:

the outer and inner tubular members are made from polyimide.

6 – 43. (Canceled).

EXHIBIT B

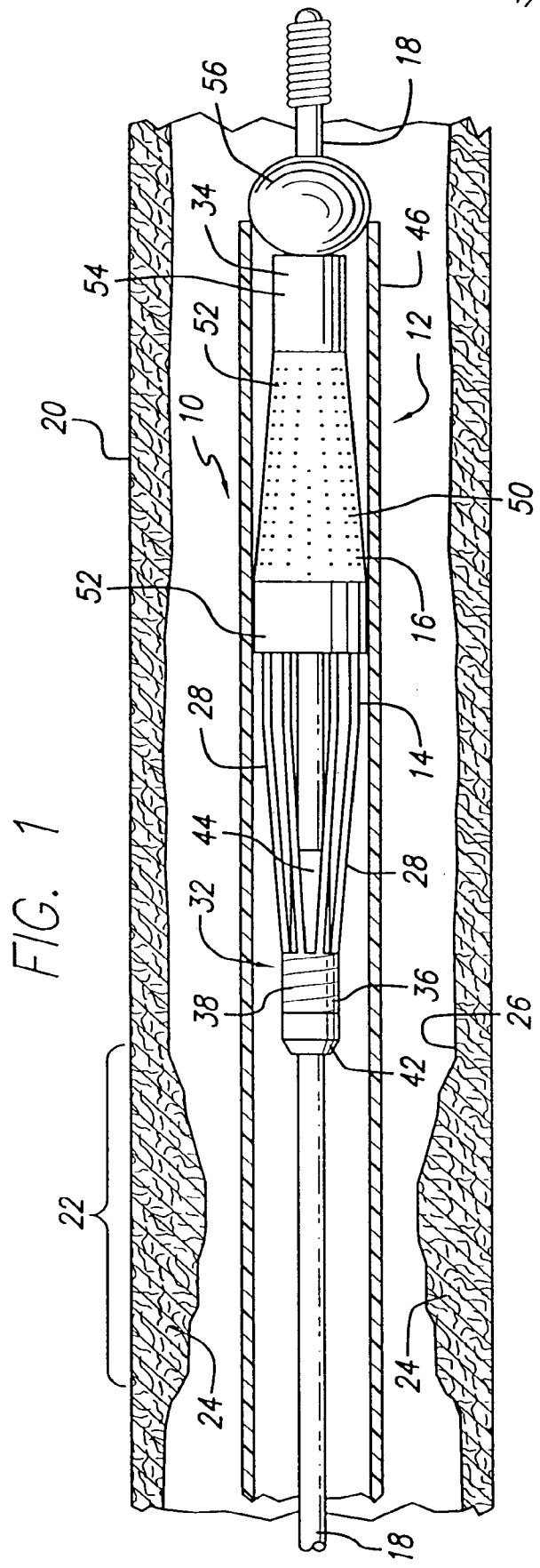
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FIG. 1

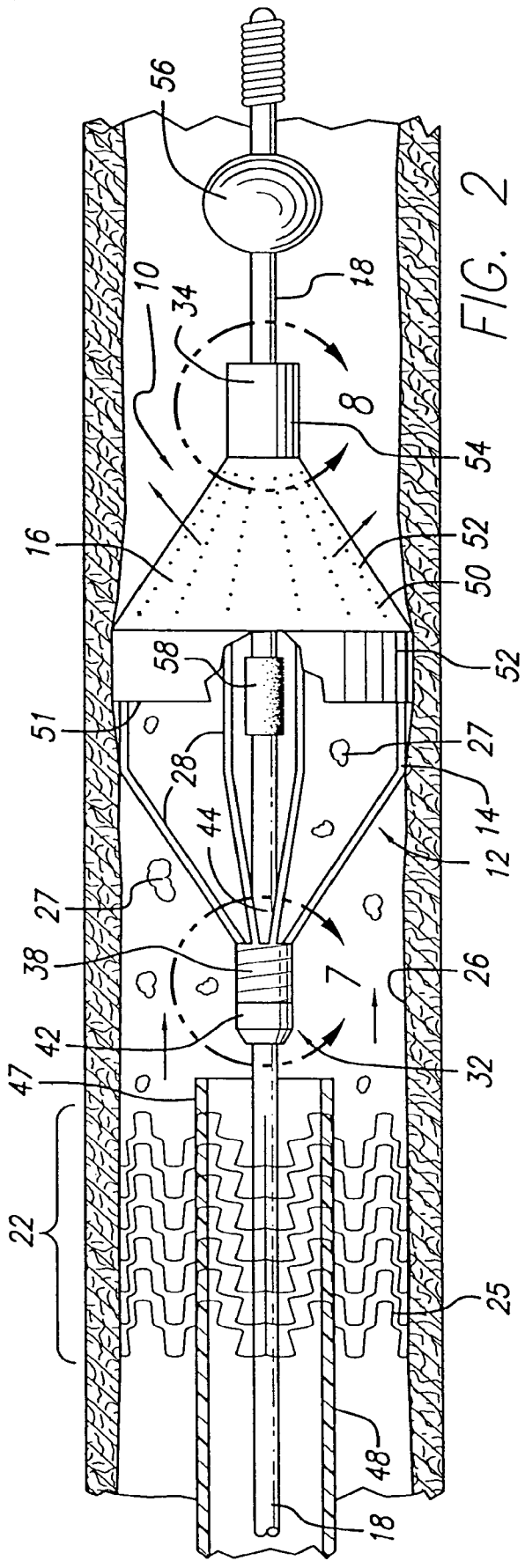
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FIG. 2

FIG. 3

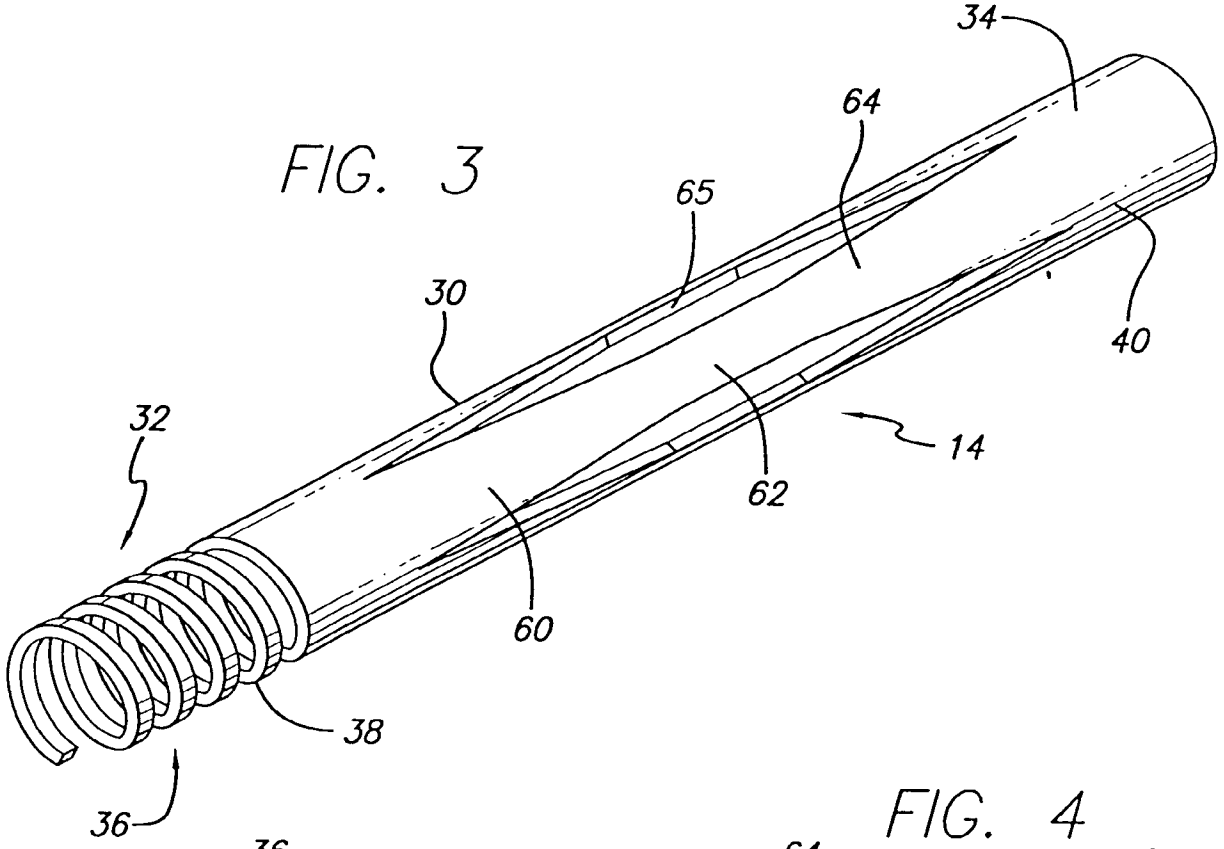


FIG. 4

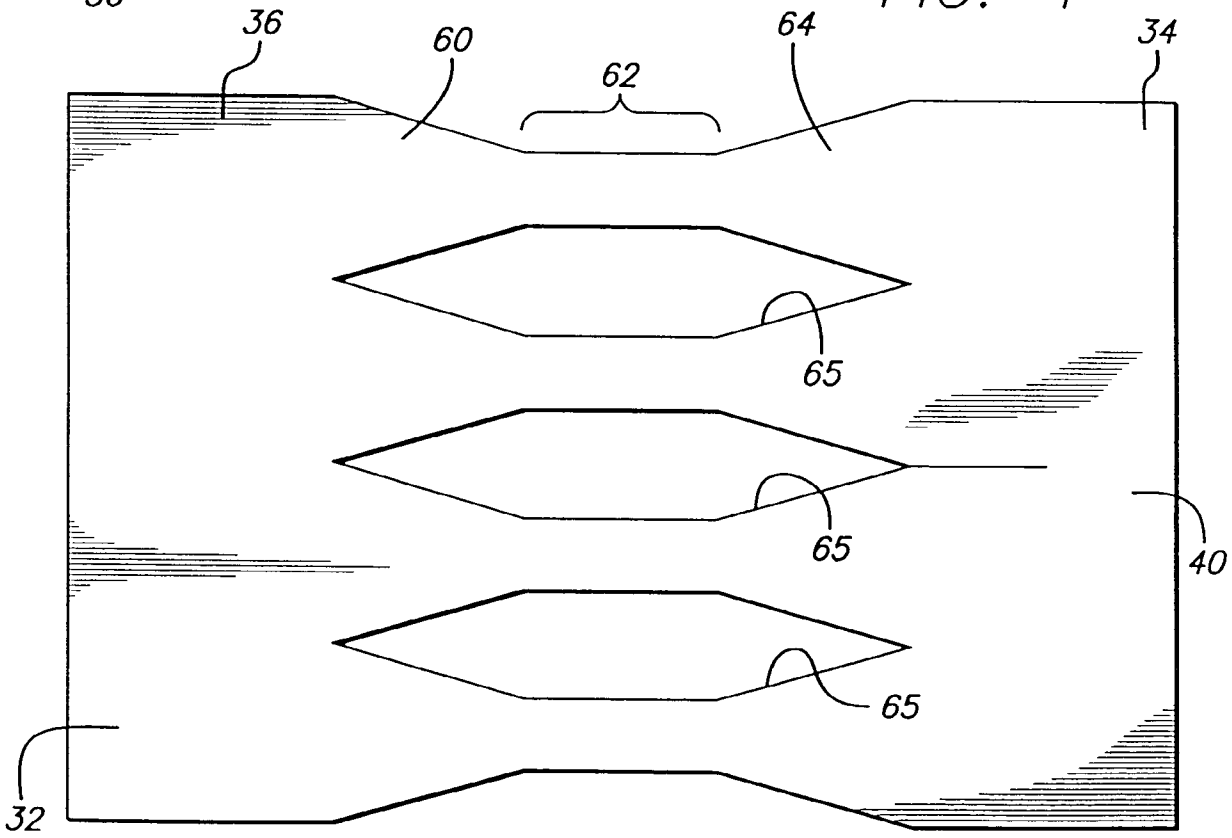


FIG. 5

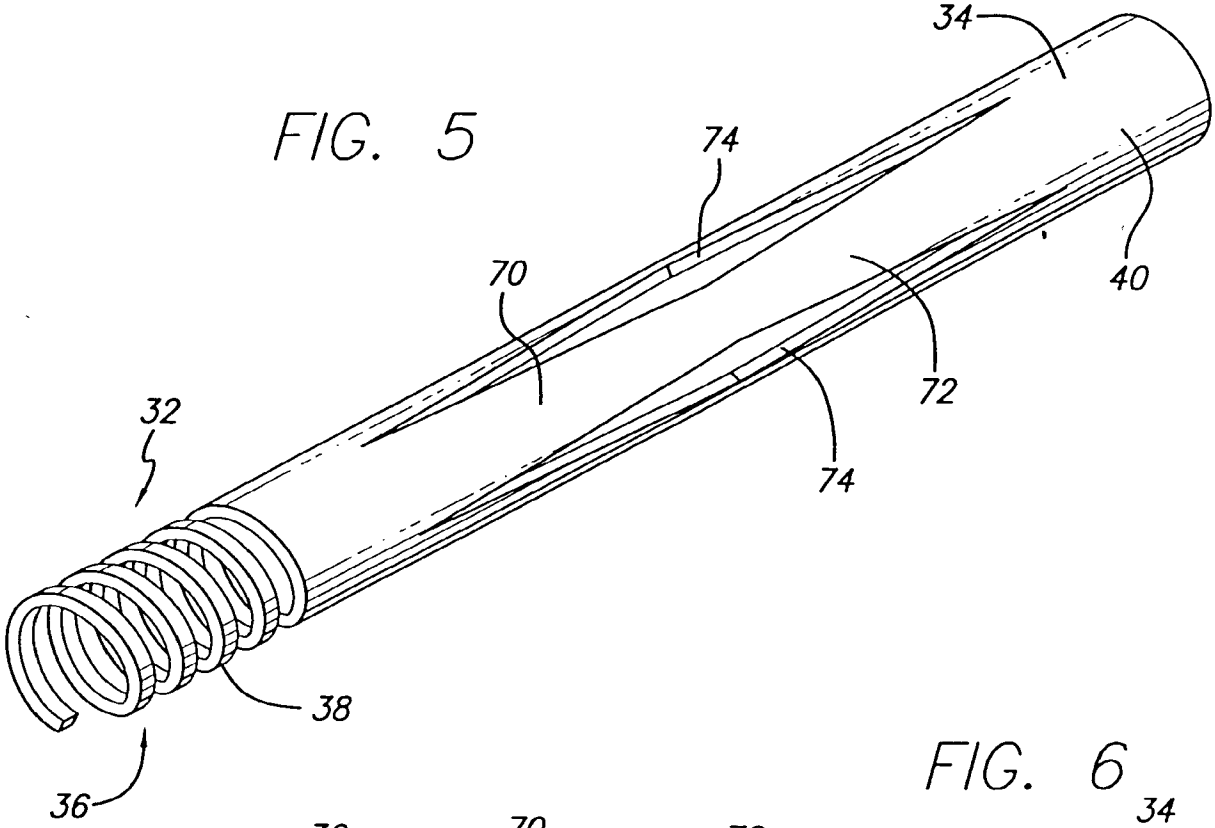
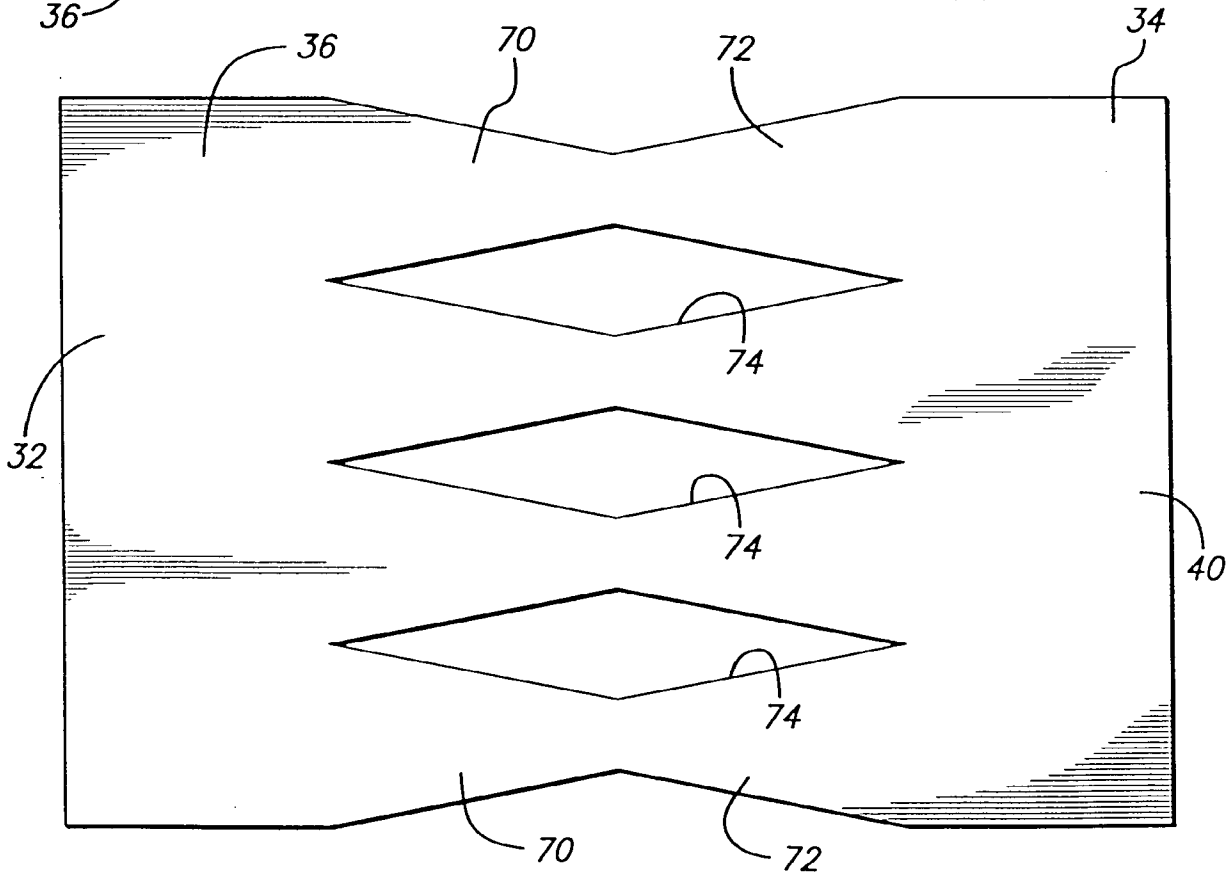
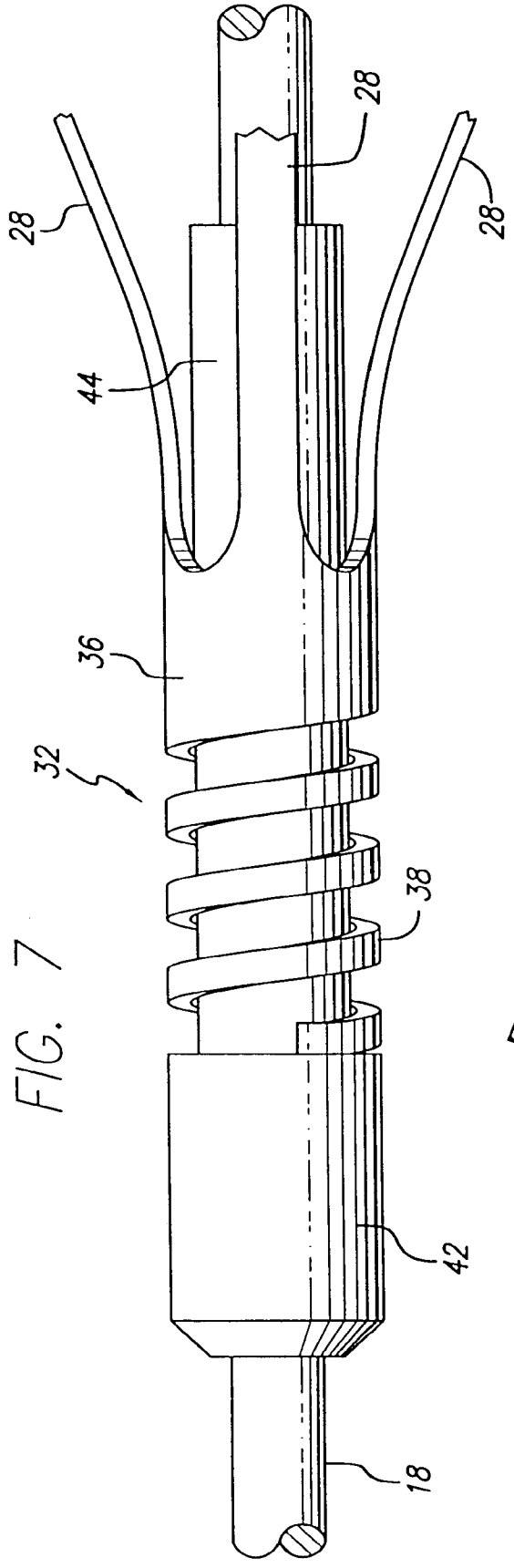


FIG. 6





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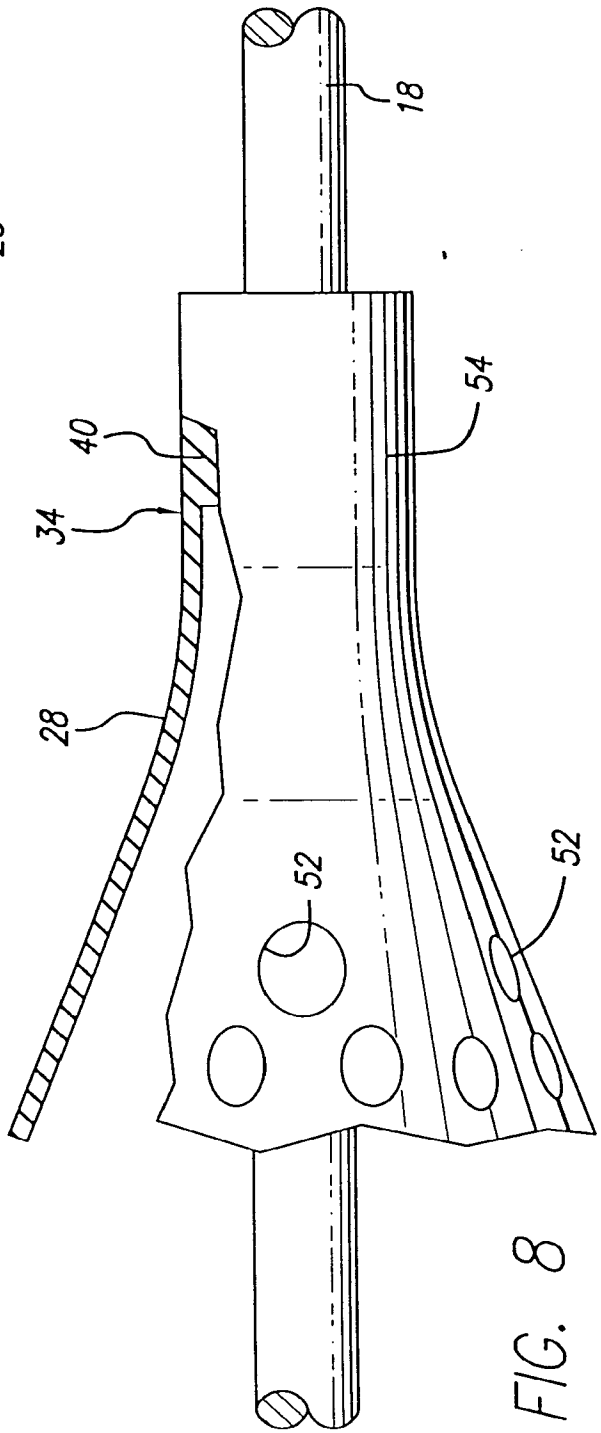

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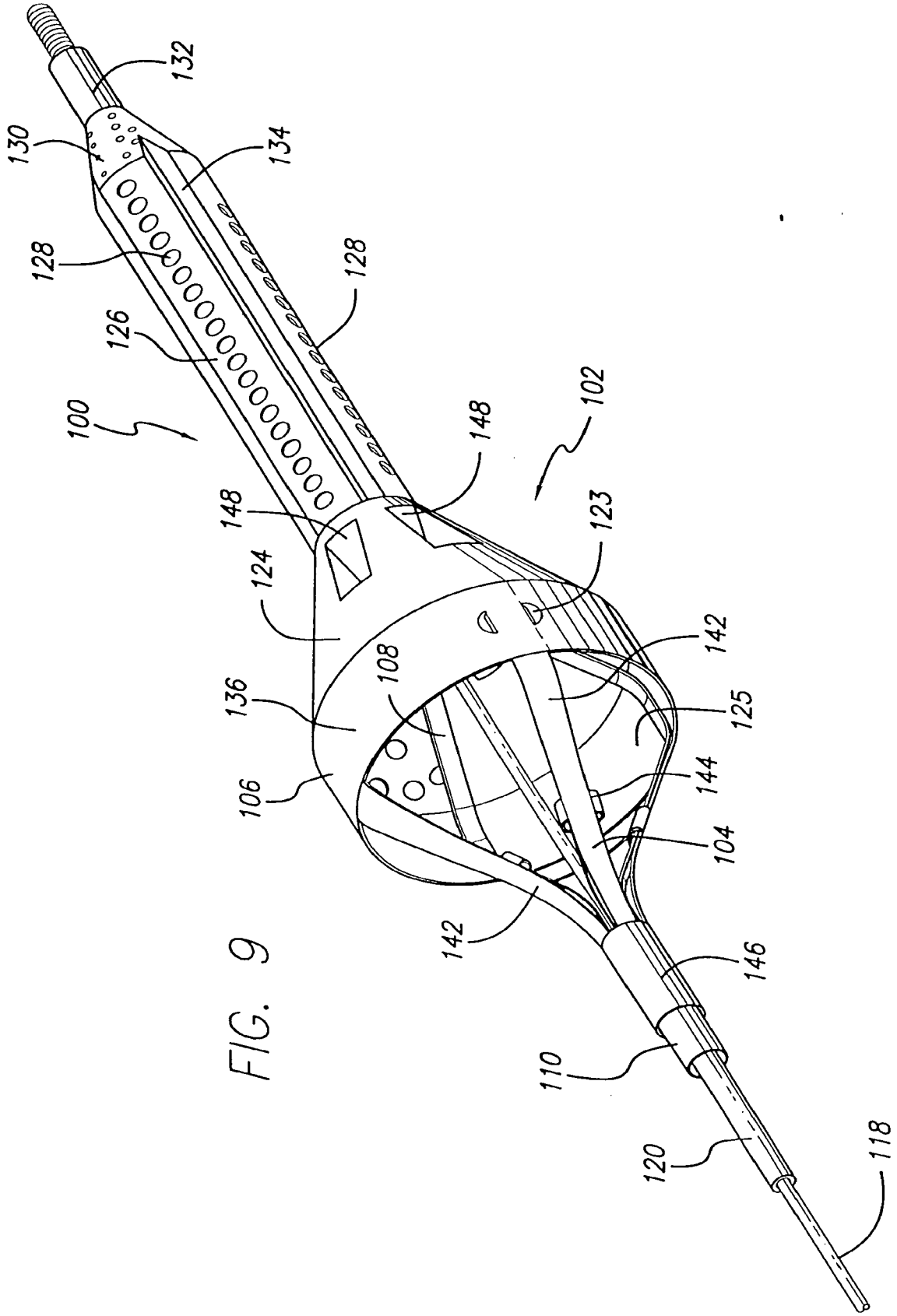
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FIG. 9

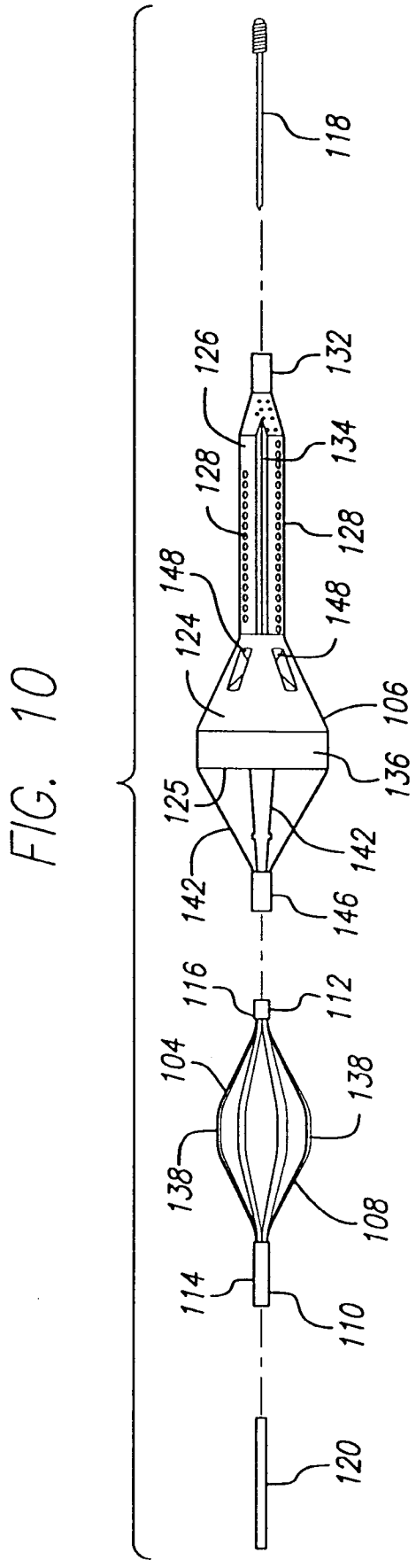
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FIG. 10

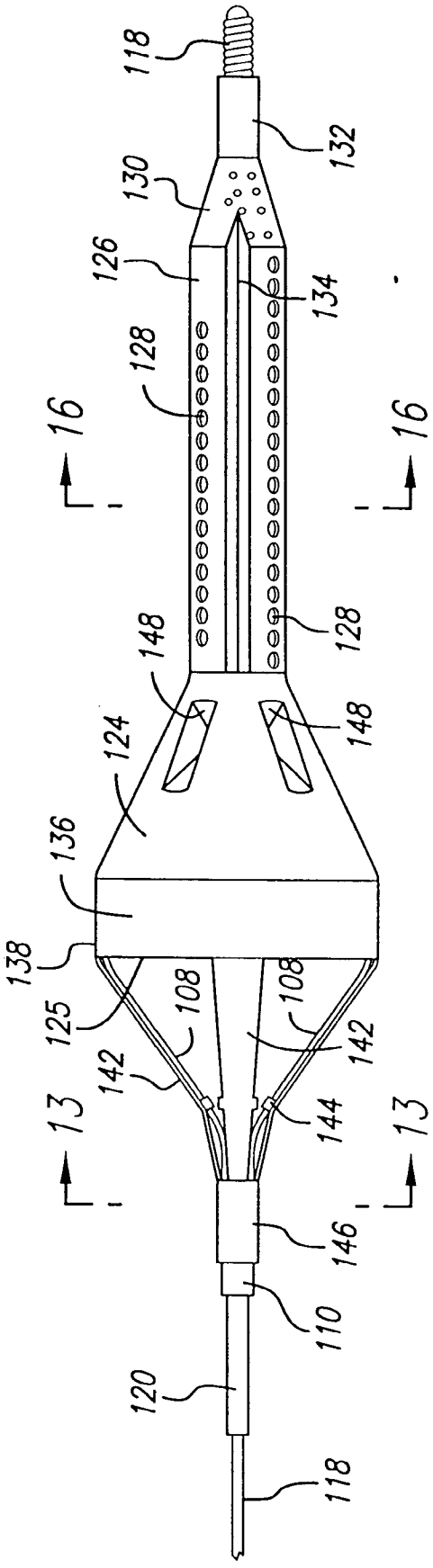
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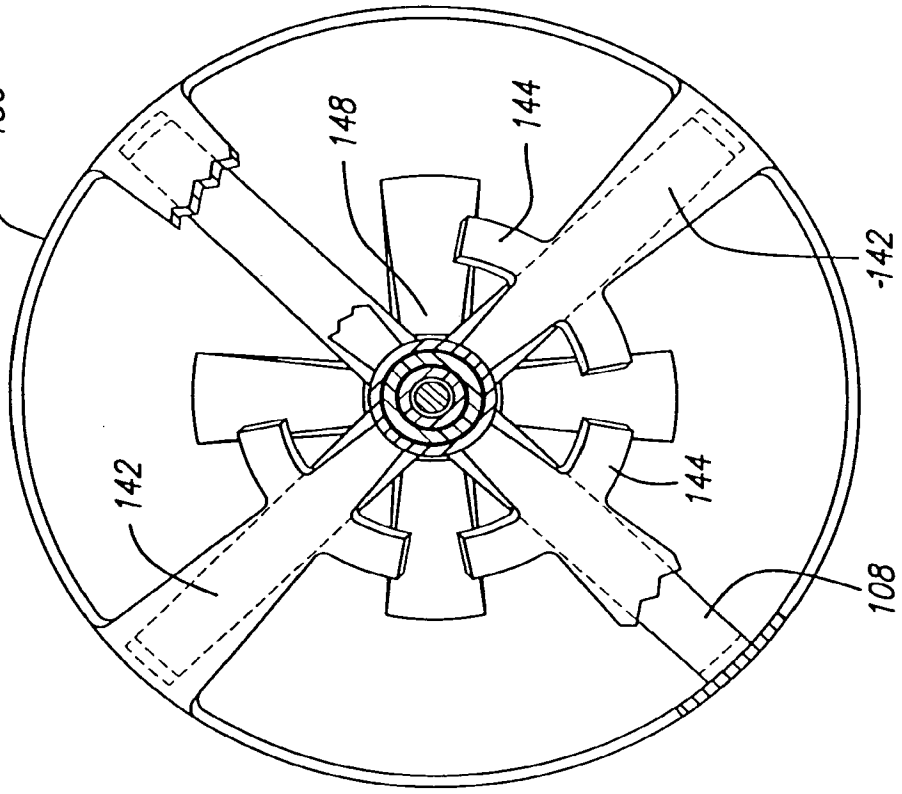
FIG. 11



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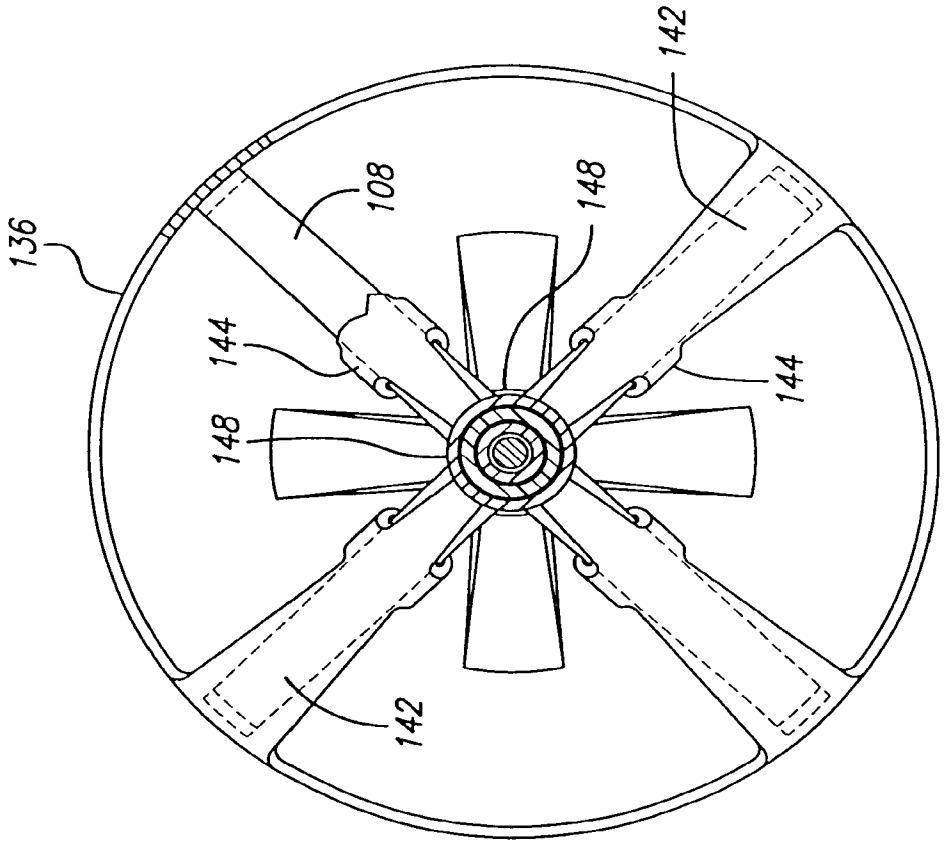
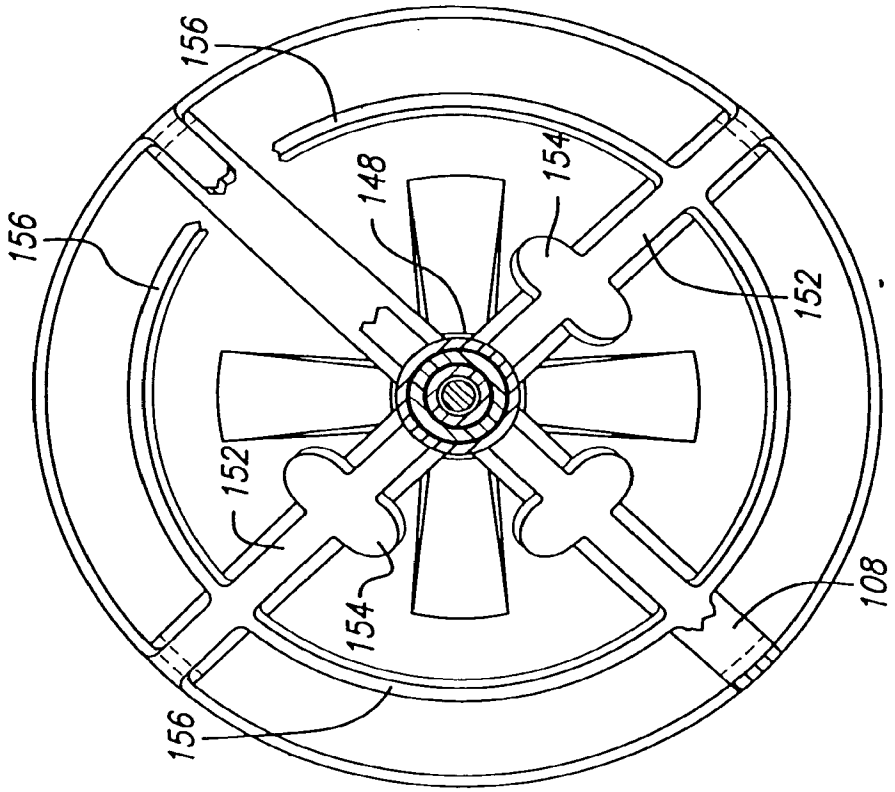


FIG. 12

FIG. 15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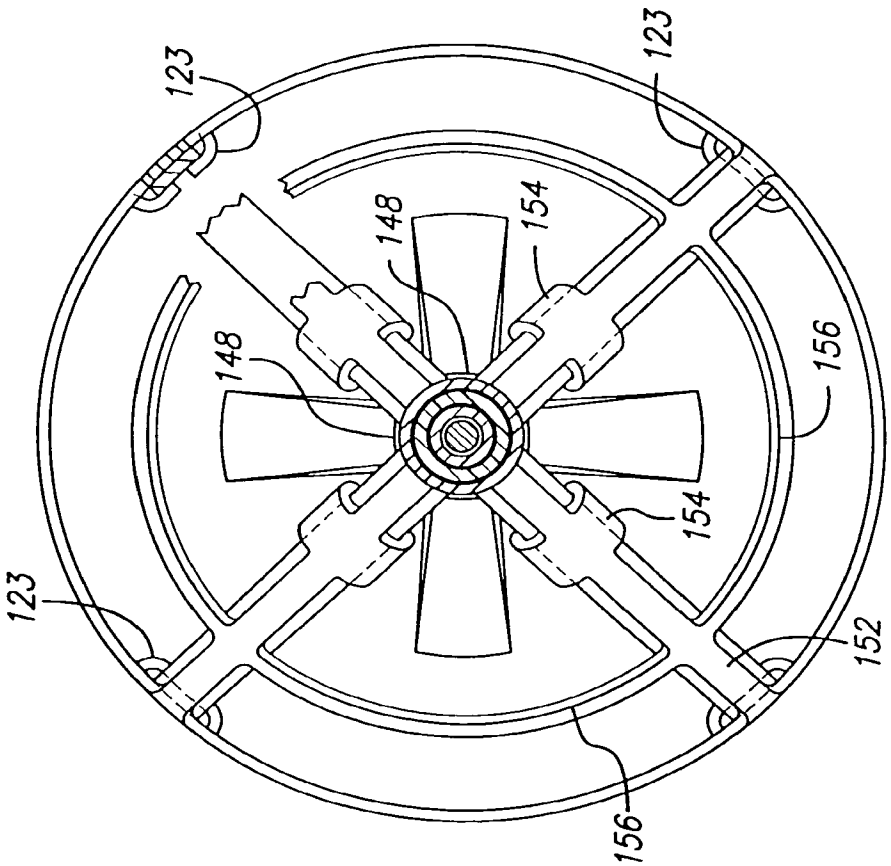
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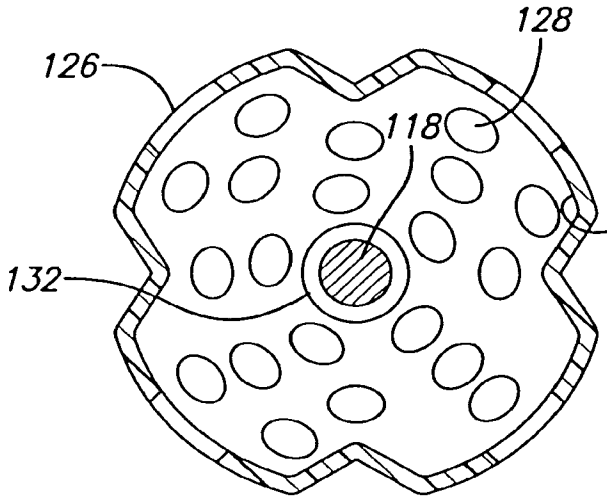

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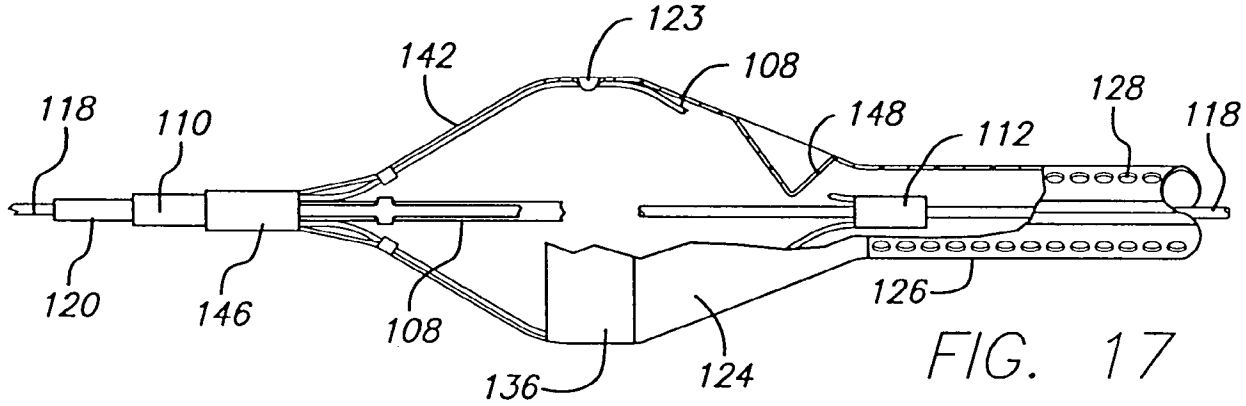

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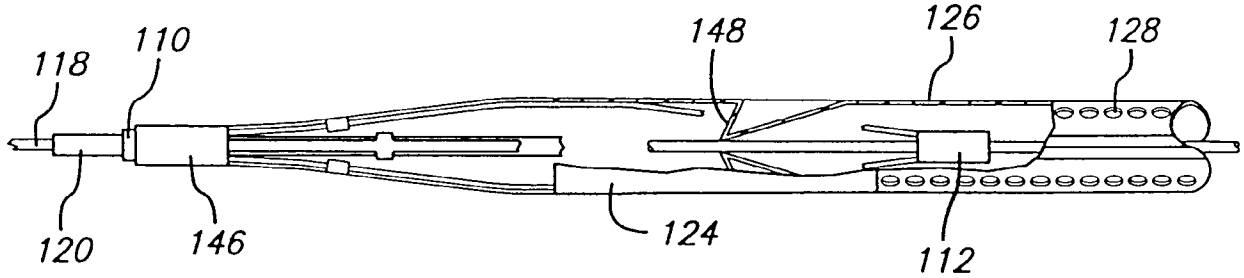

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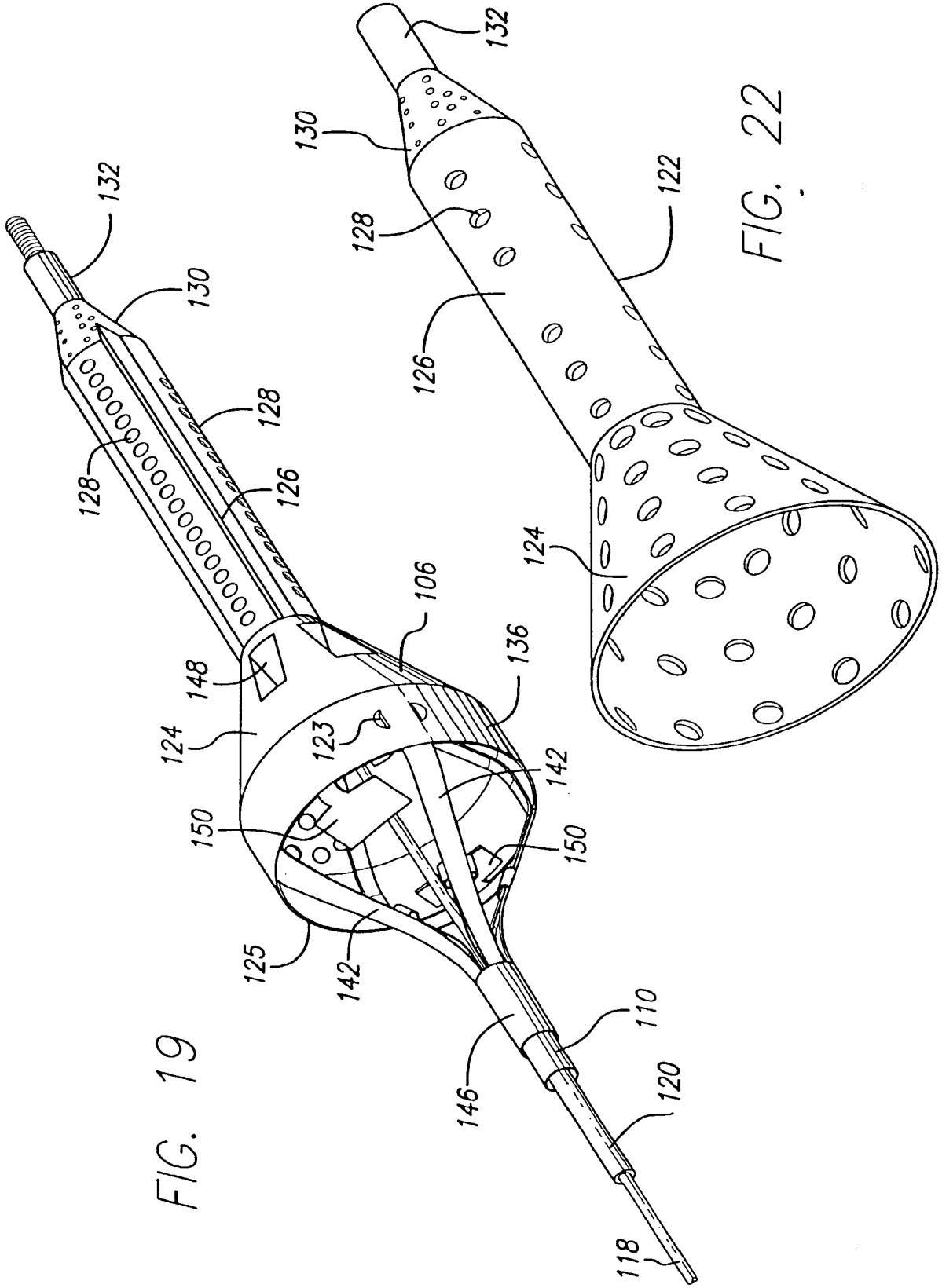
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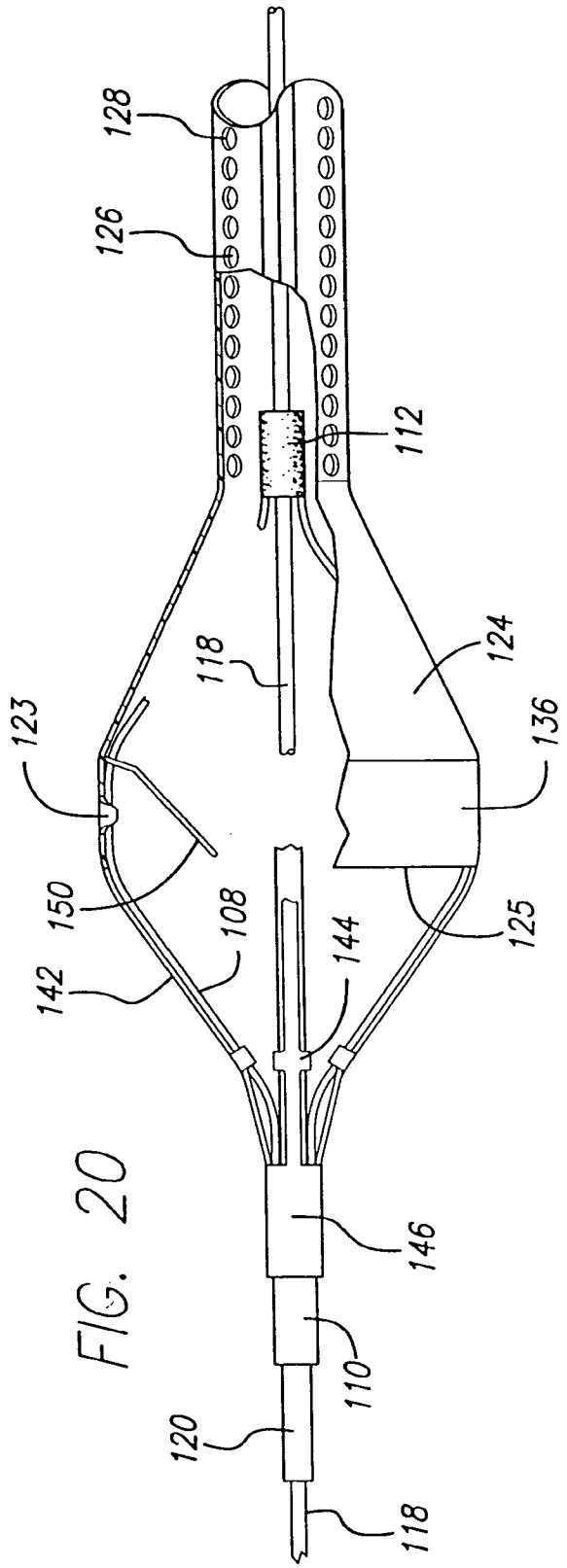
FIG. 19

FIG. 22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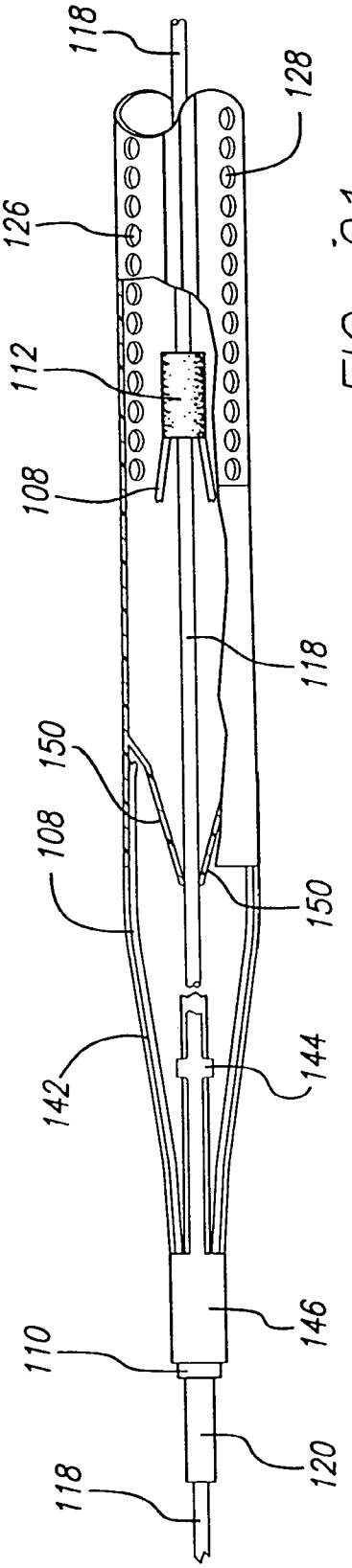
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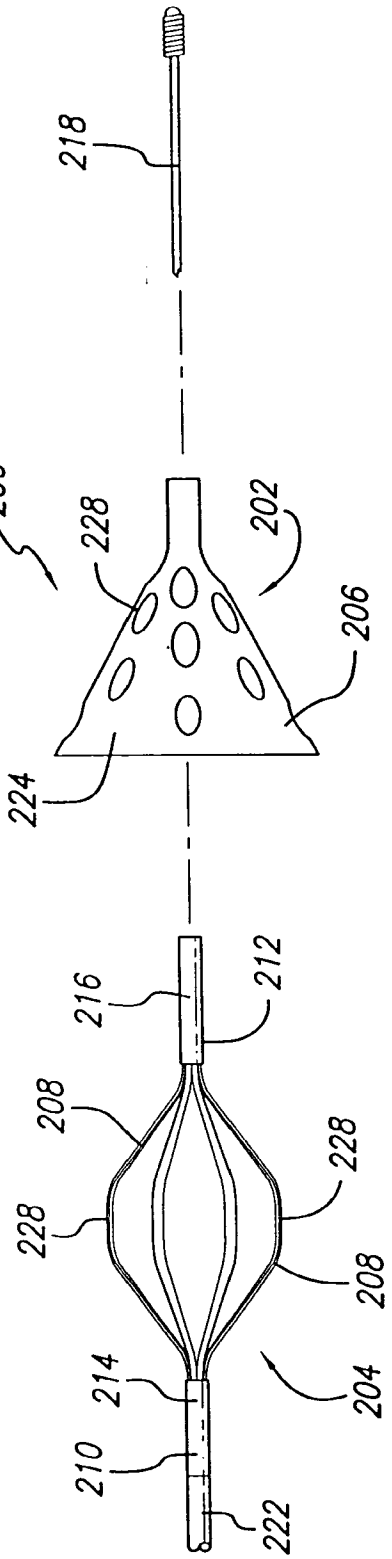
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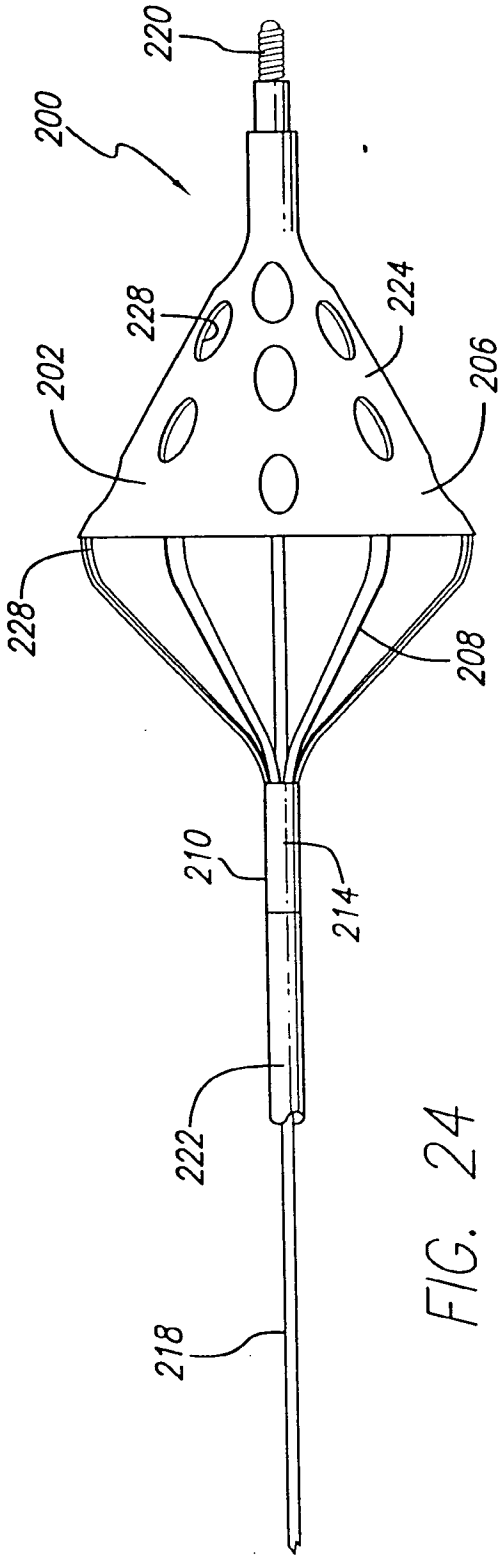
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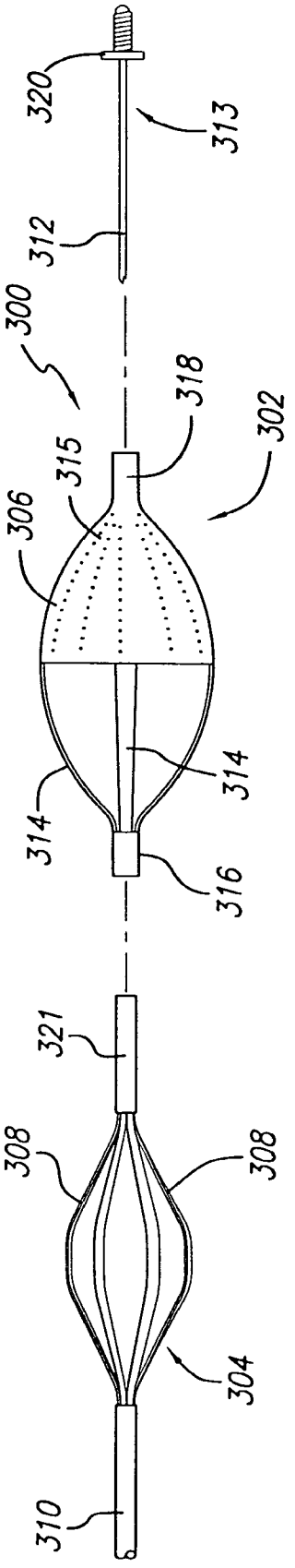
FIG. 24

FIG. 25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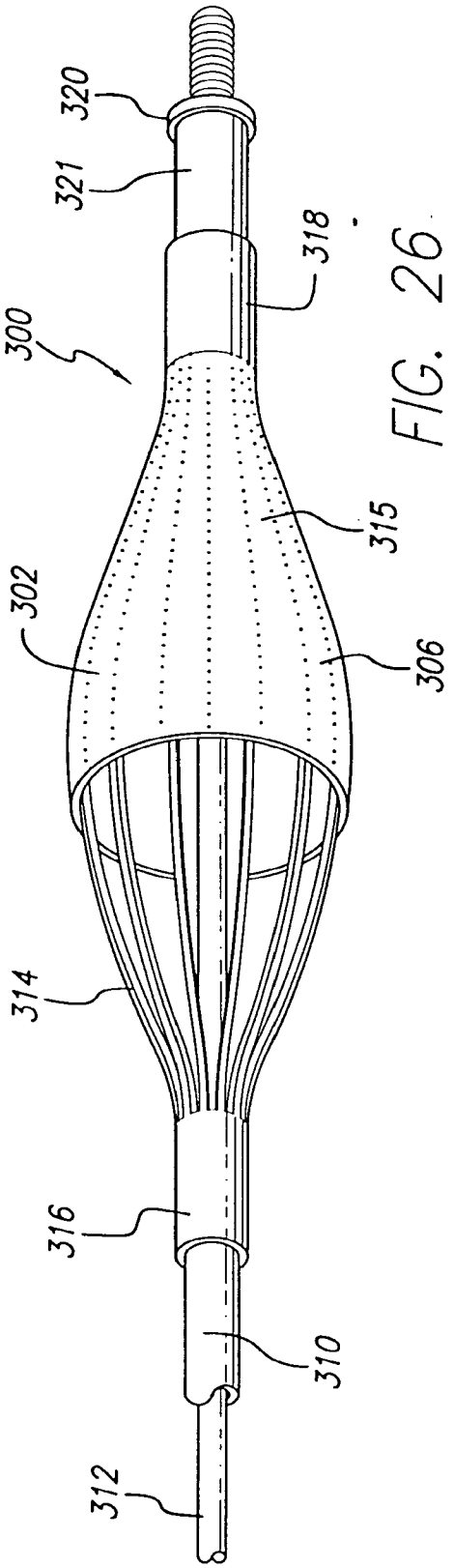
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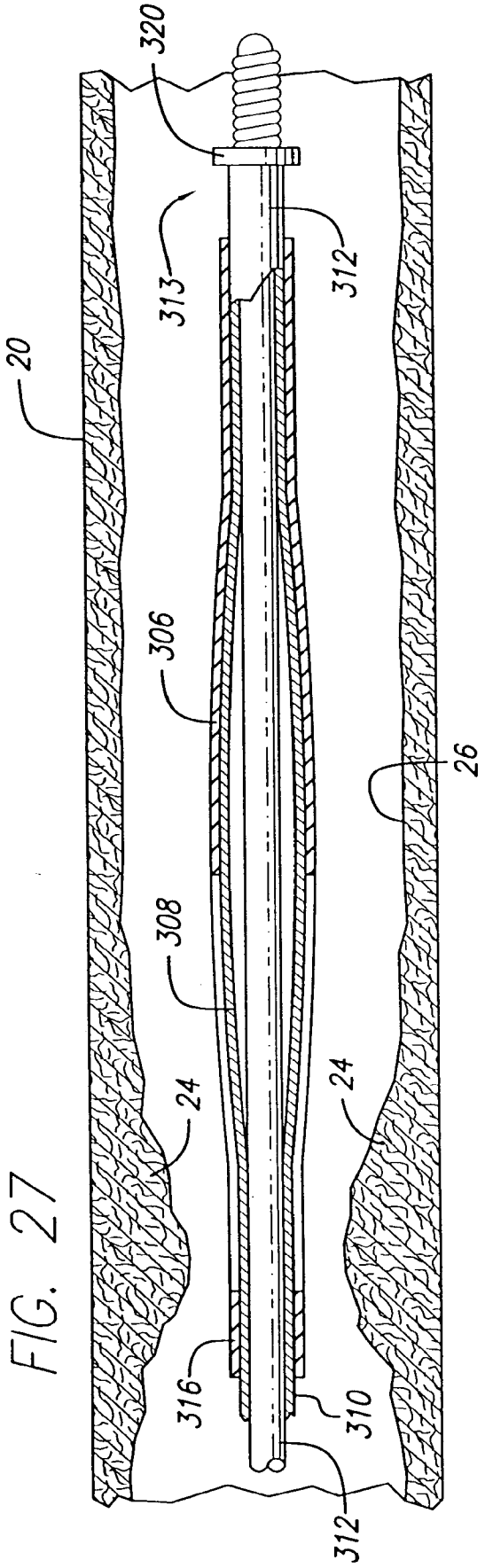
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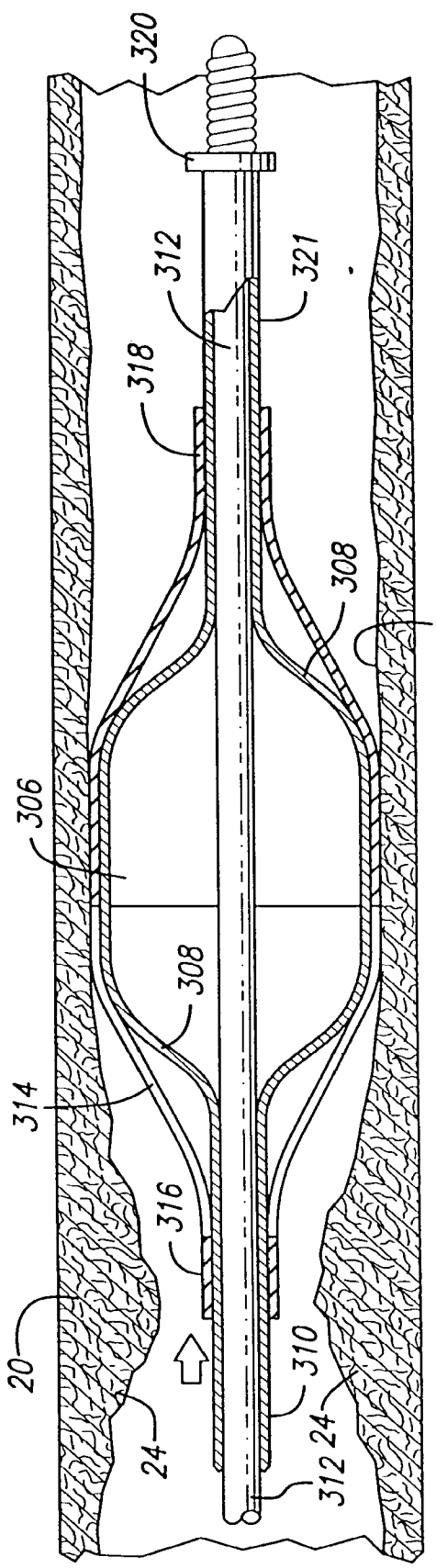
FIG. 27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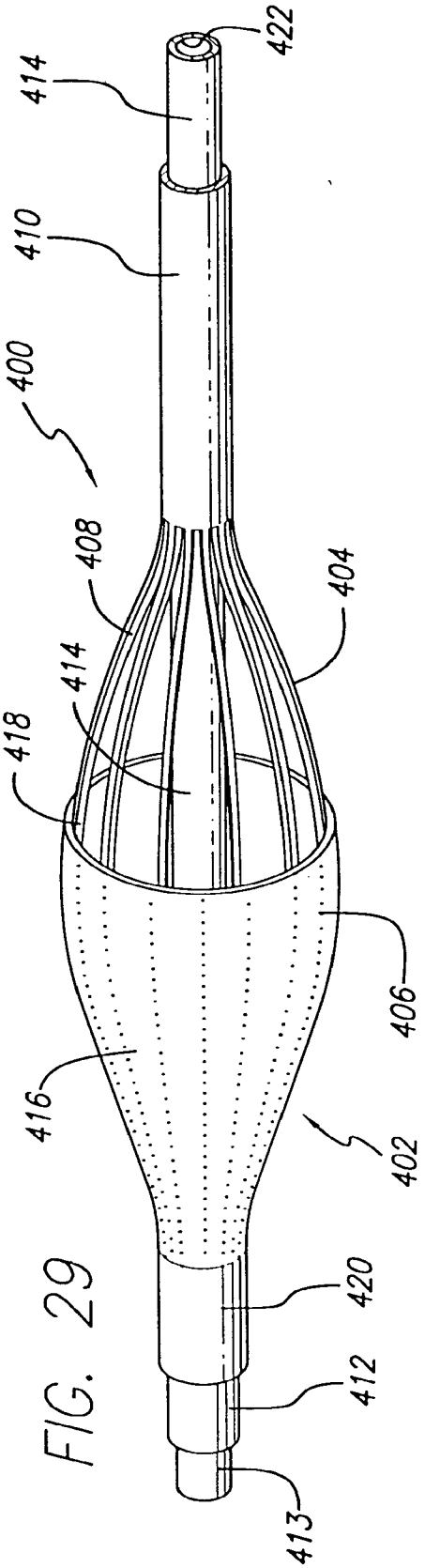
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FIG. 29

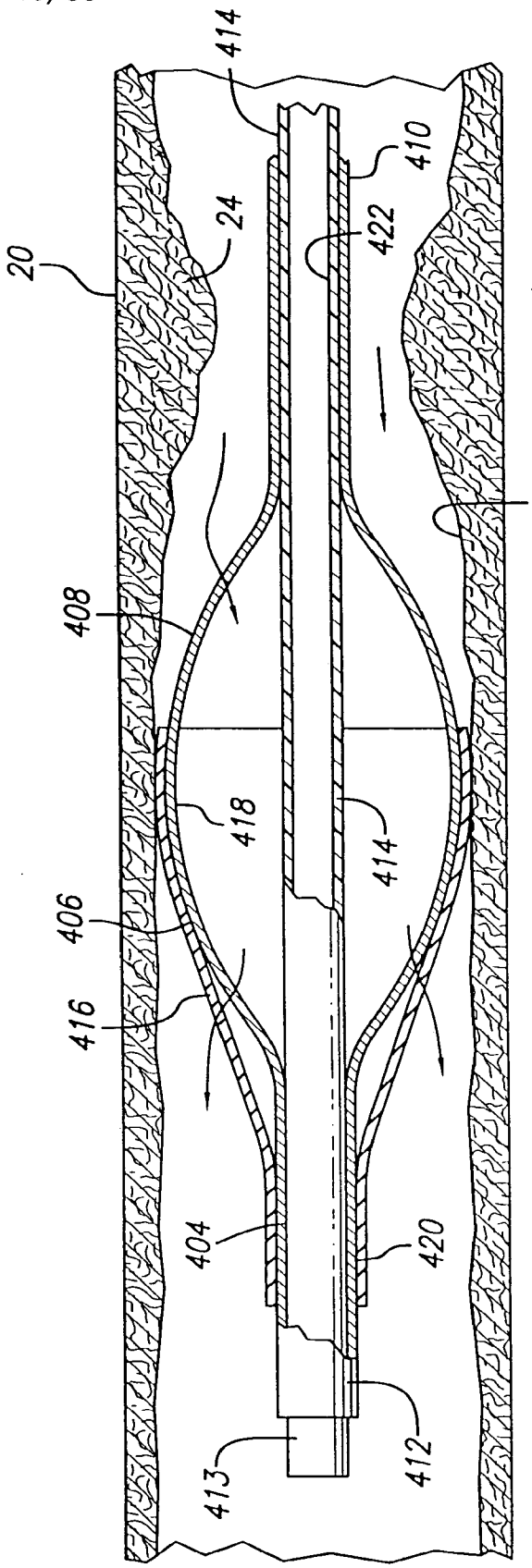
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FIG. 30

FIG. 31

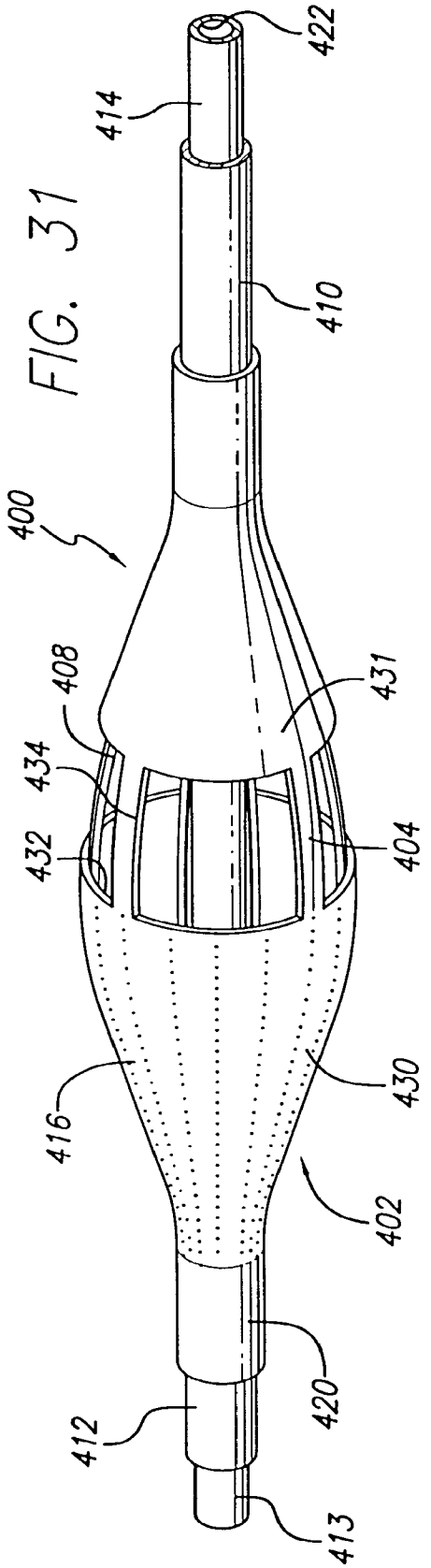
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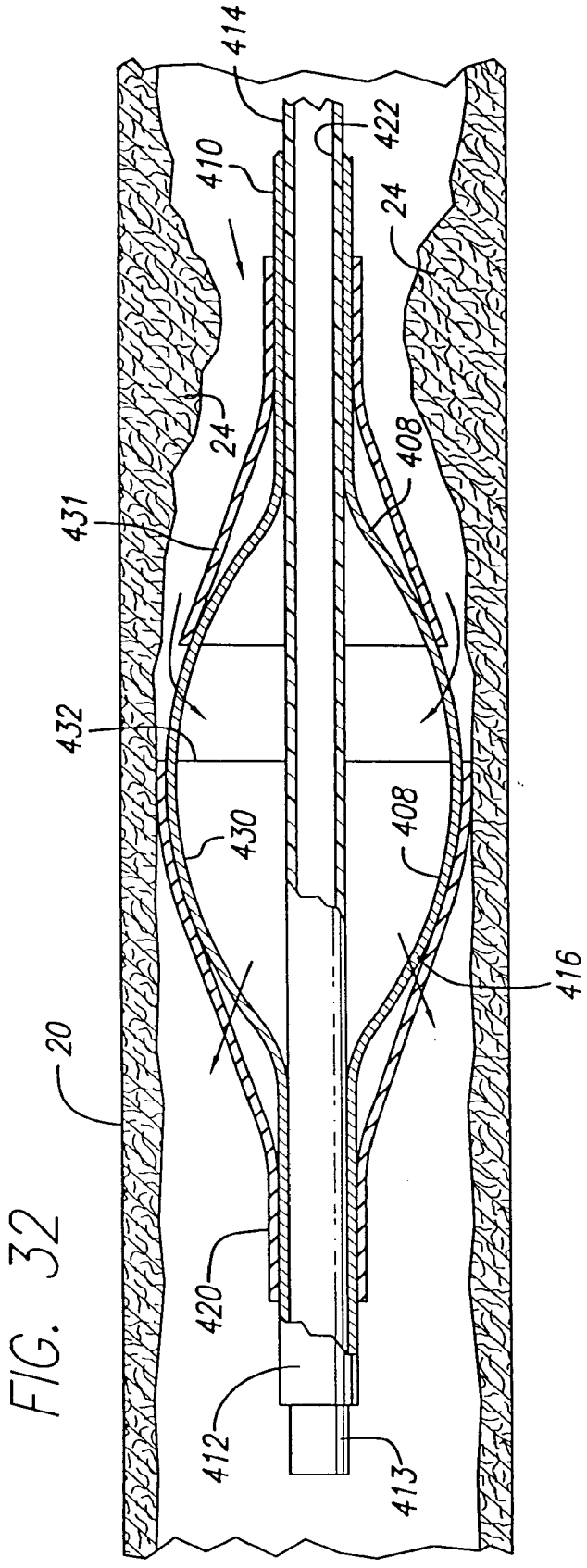
FIG. 32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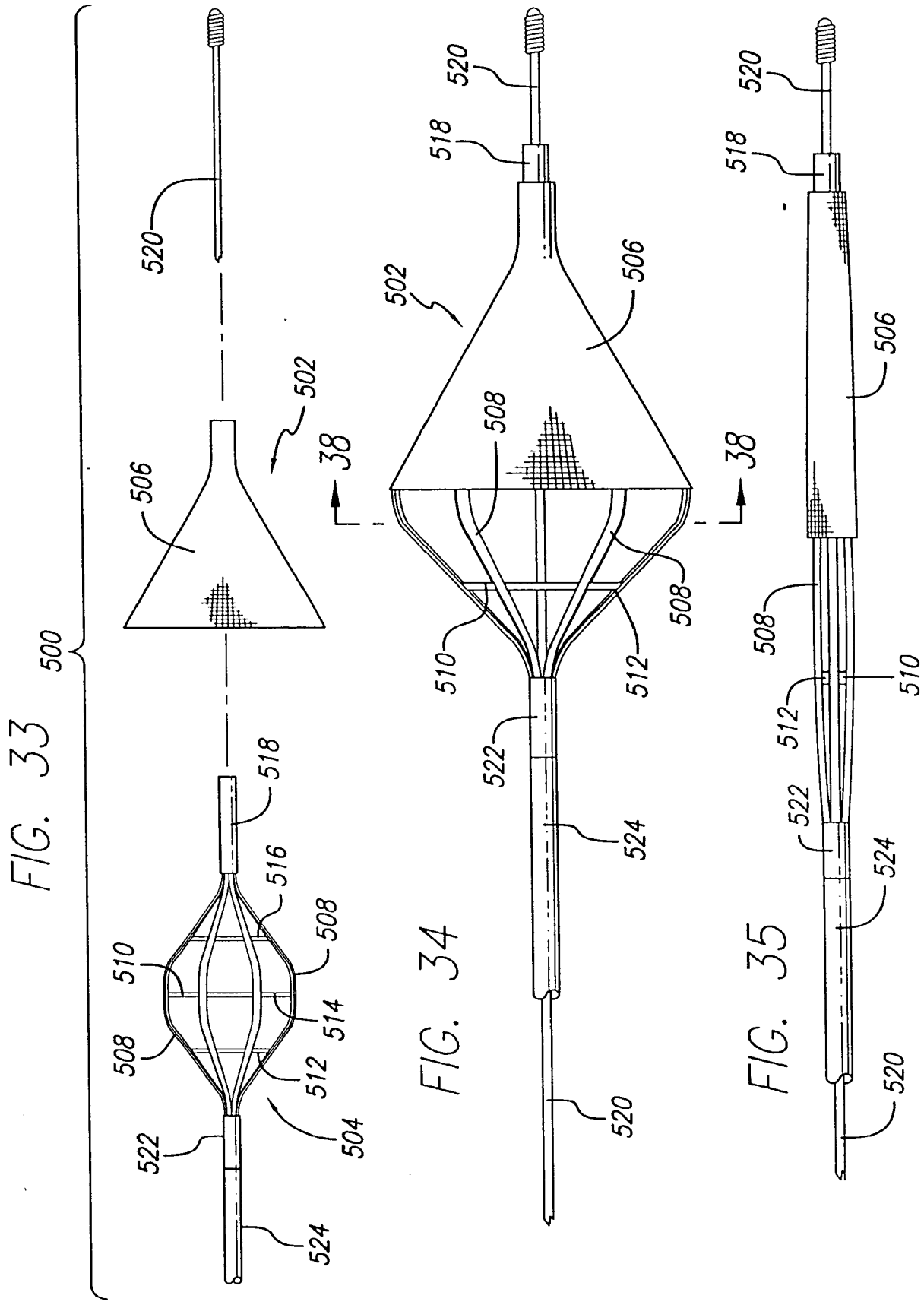
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FIG. 35

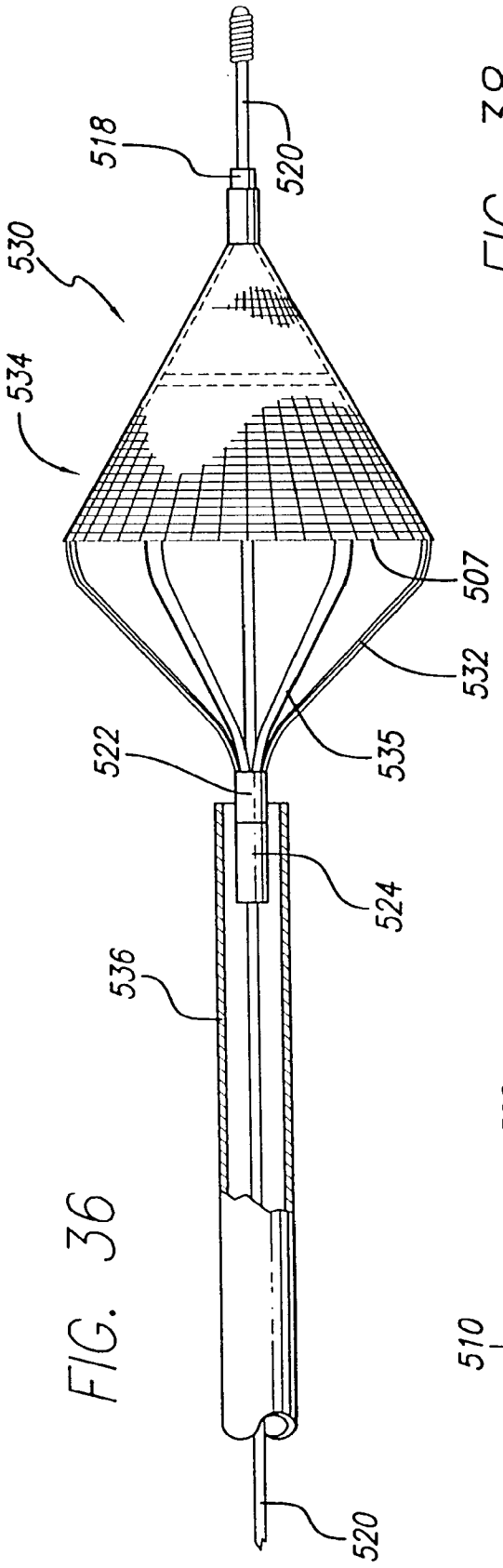

FIG. 36

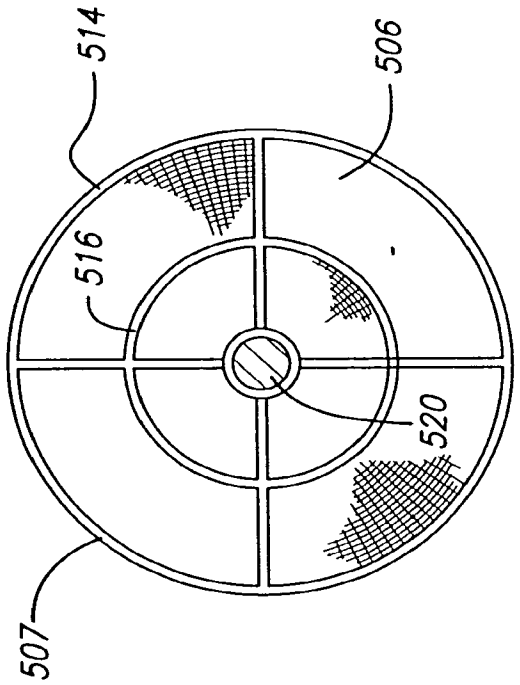

FIG. 38

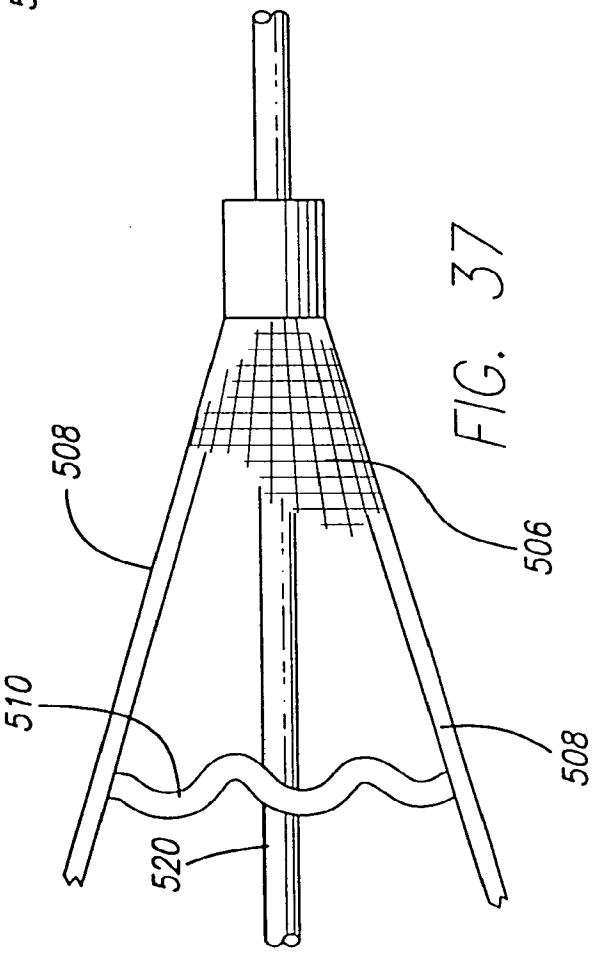

FIG. 37

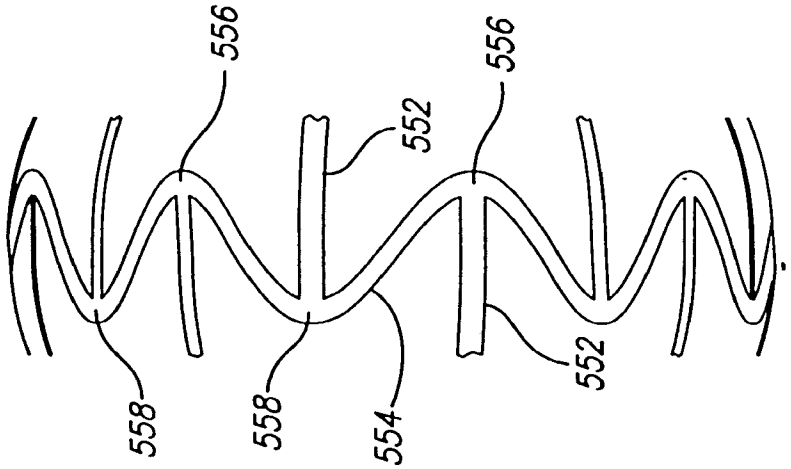

FIG. 40

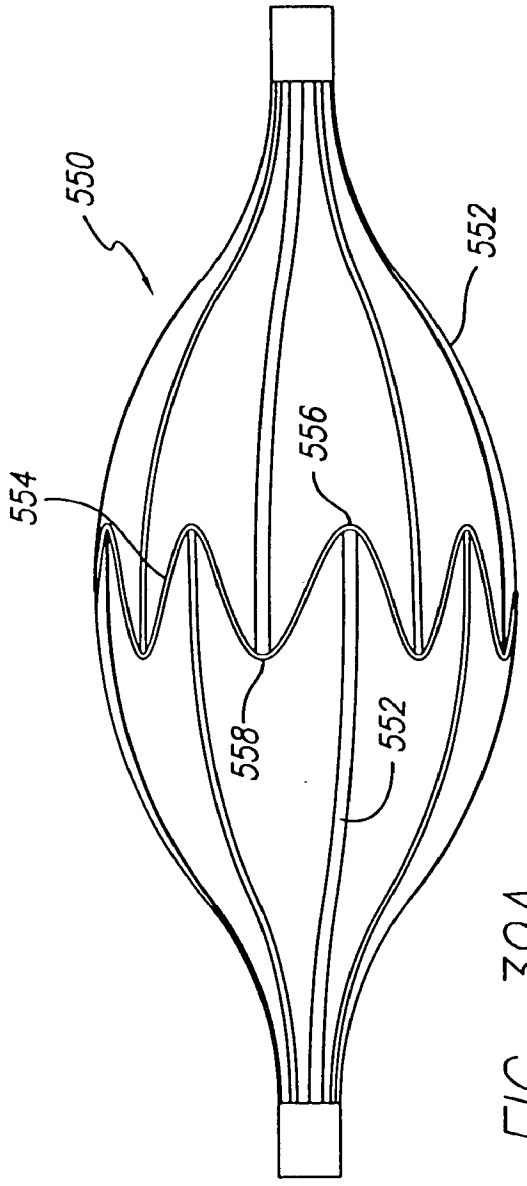

FIG. 39A

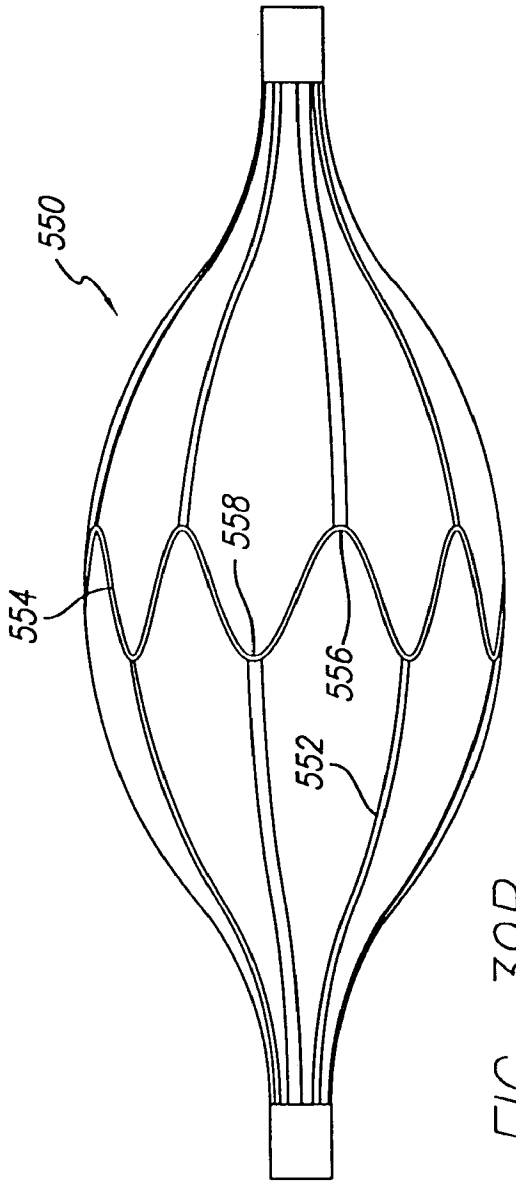

FIG. 39B

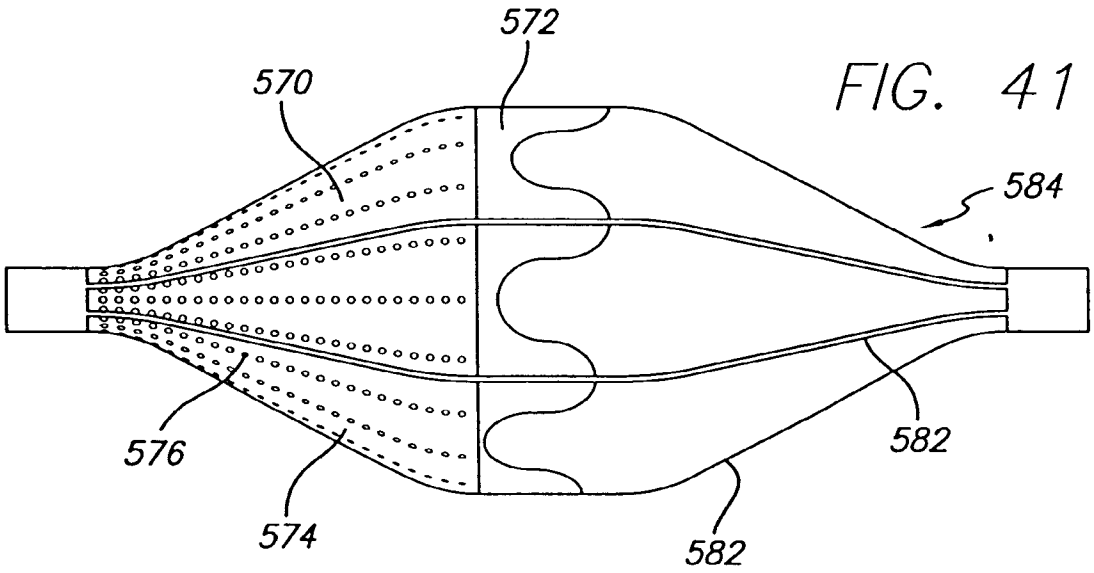
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FIG. 41

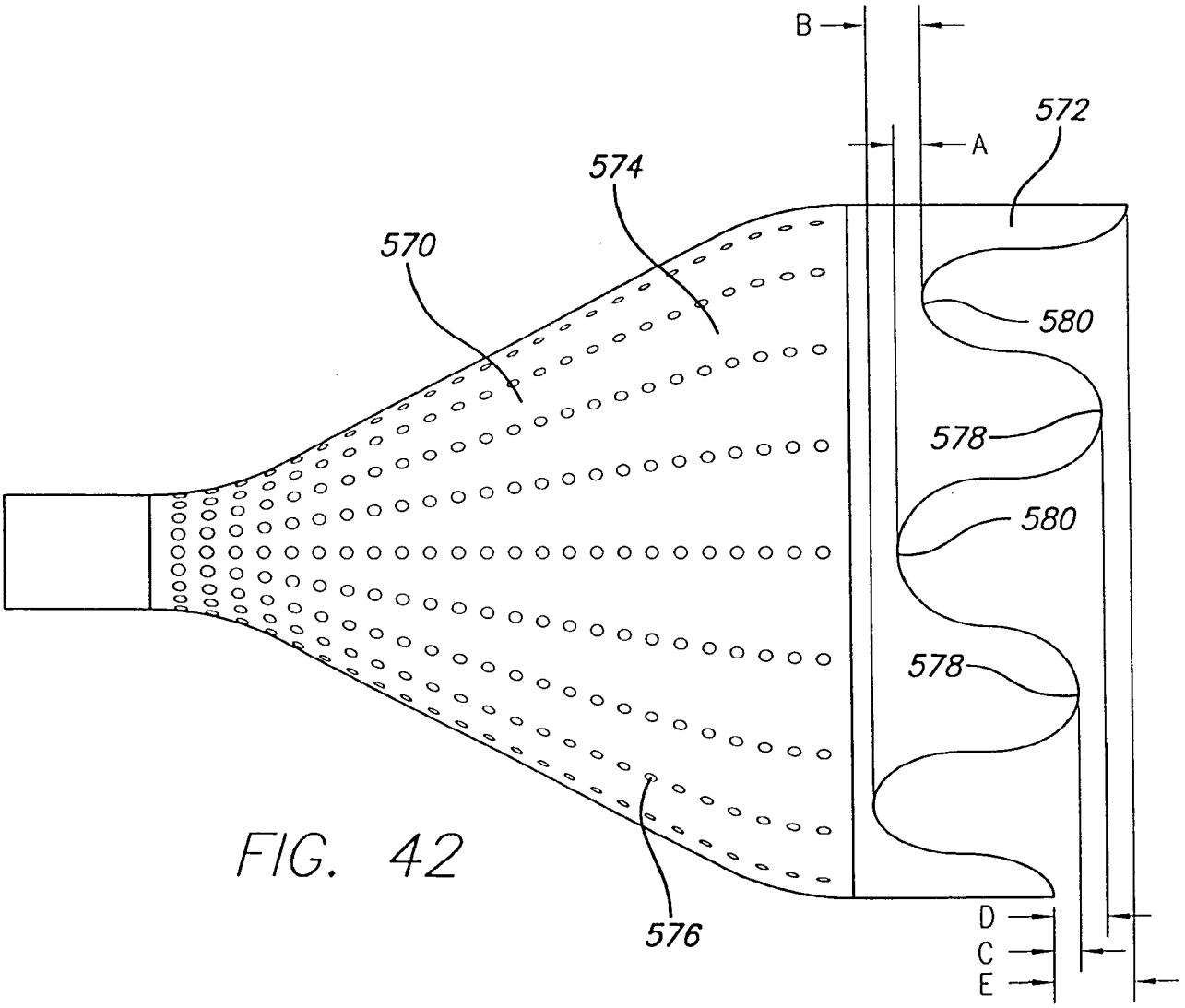
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FIG. 42

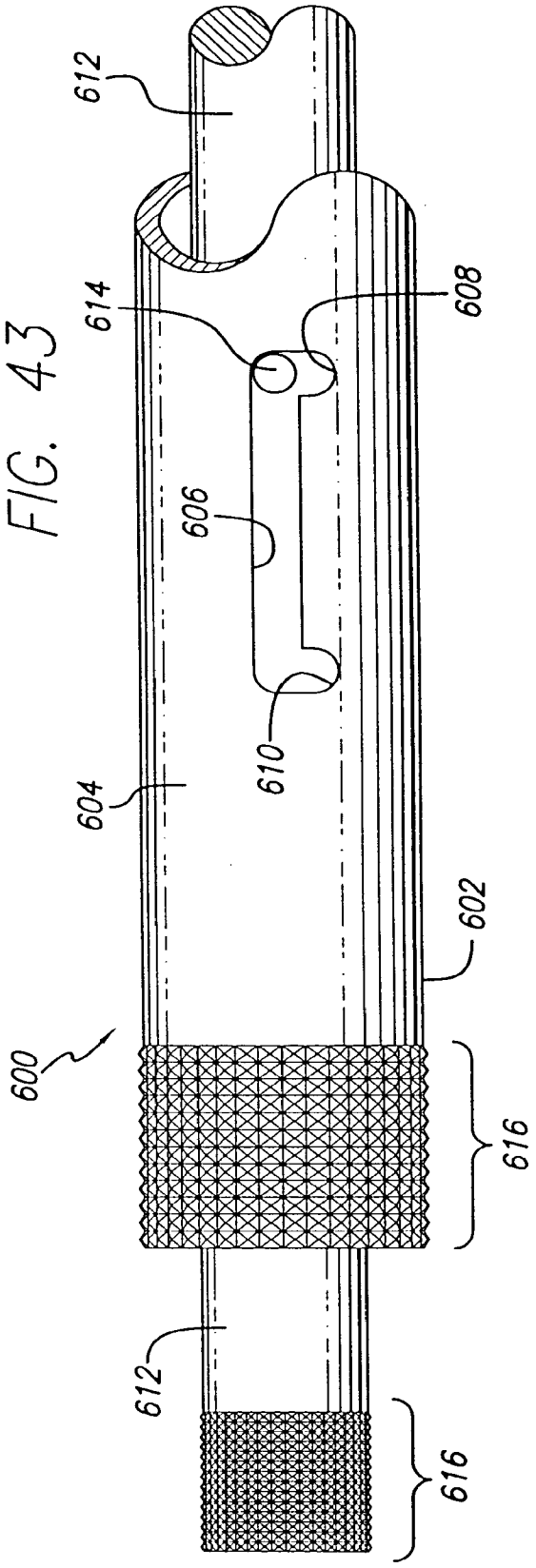
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FIG. 43

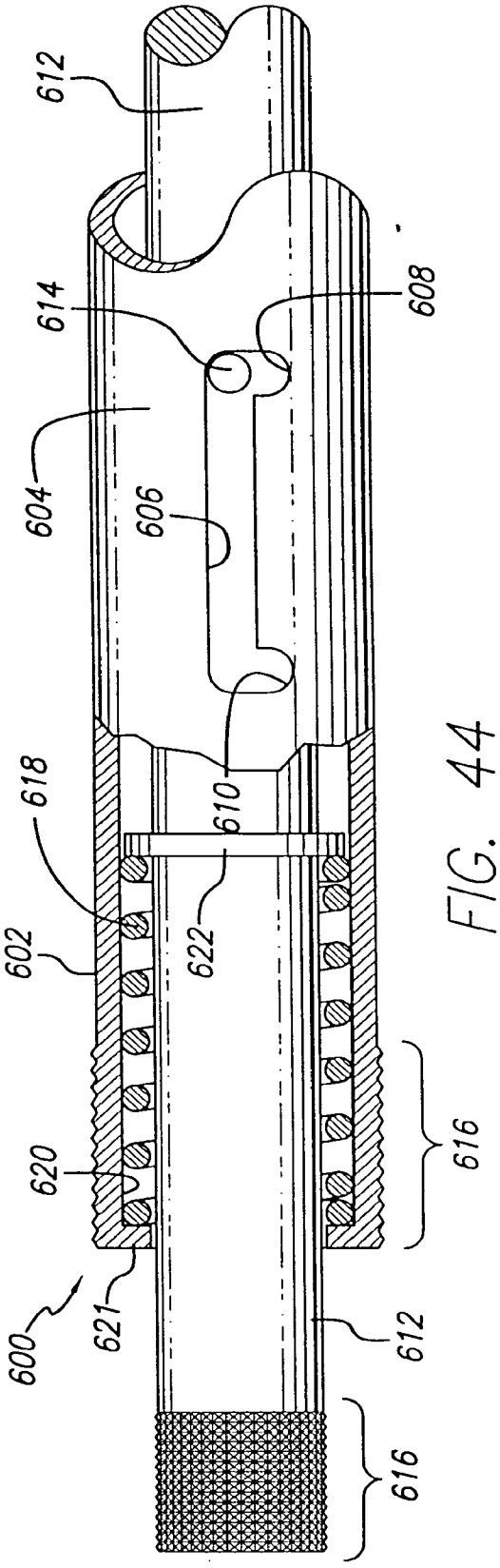
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FIG. 44

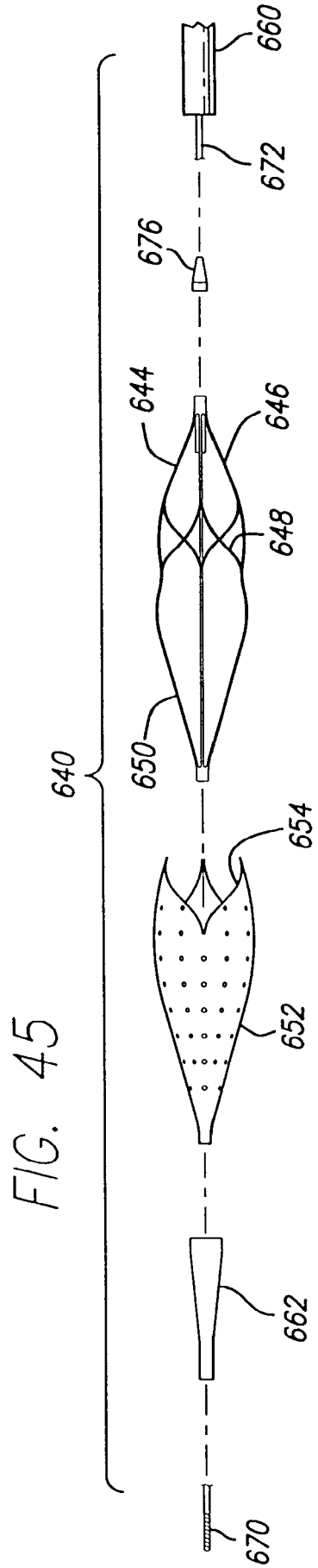

FIG. 45

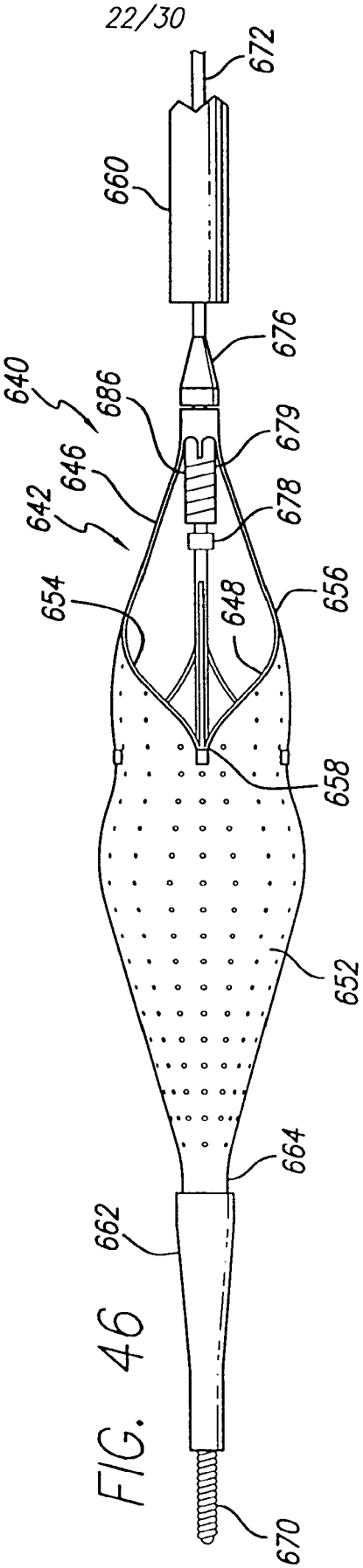

FIG. 46

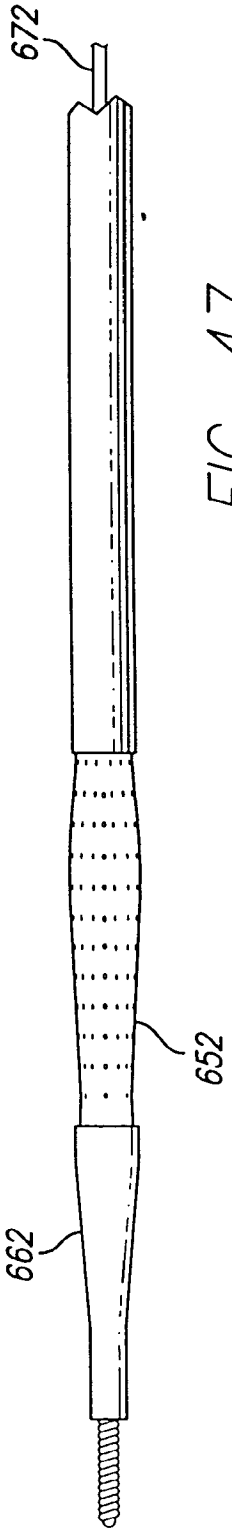

FIG. 47

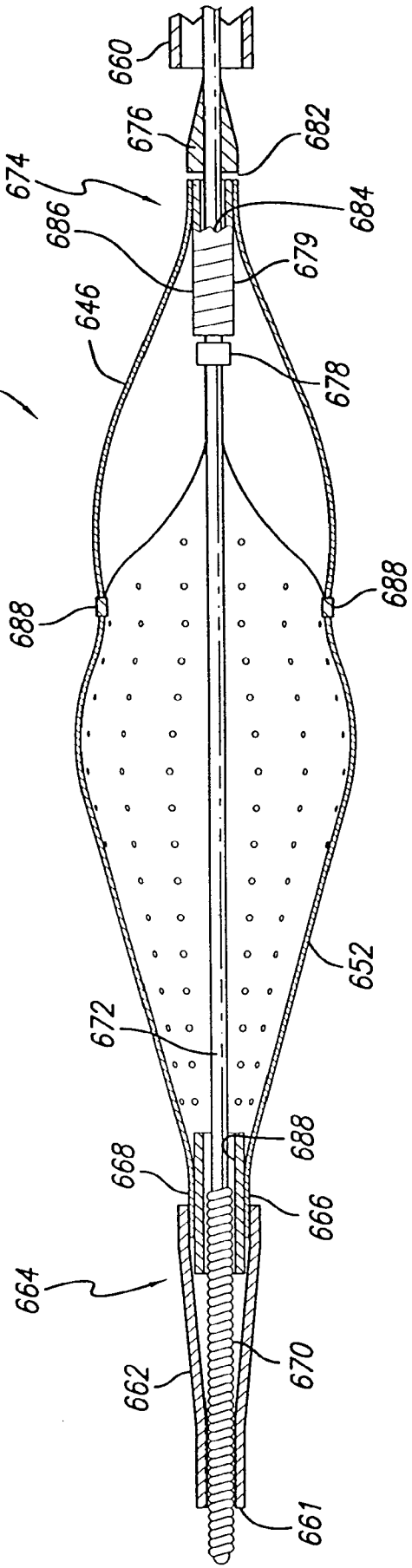
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FIG. 48

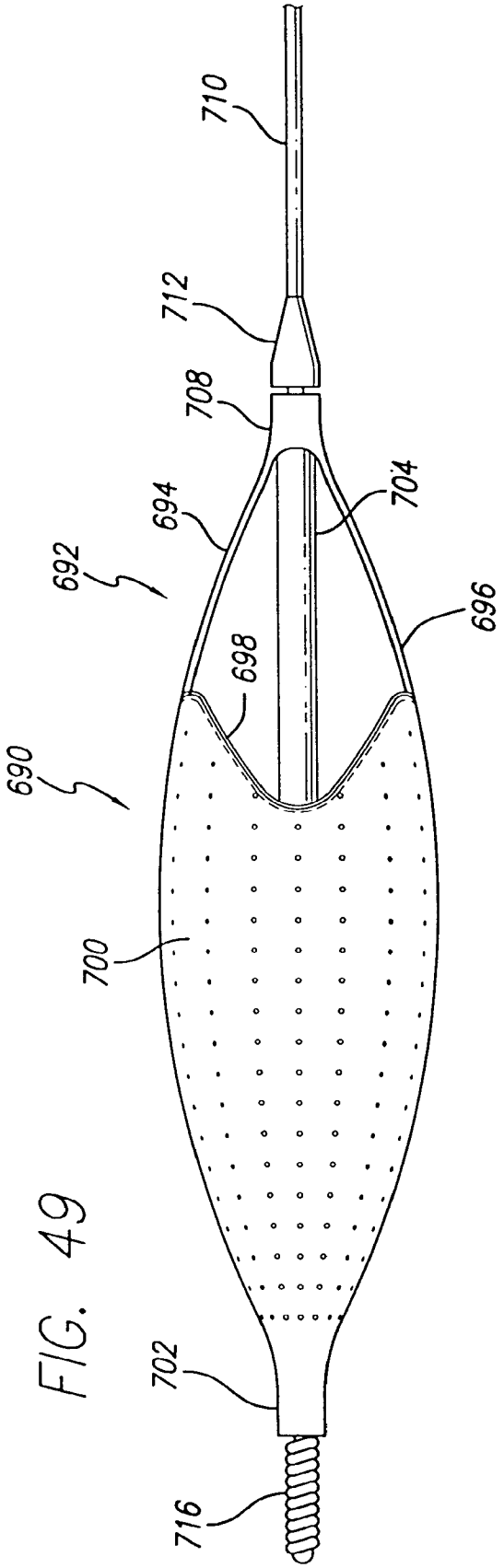
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FIG. 49

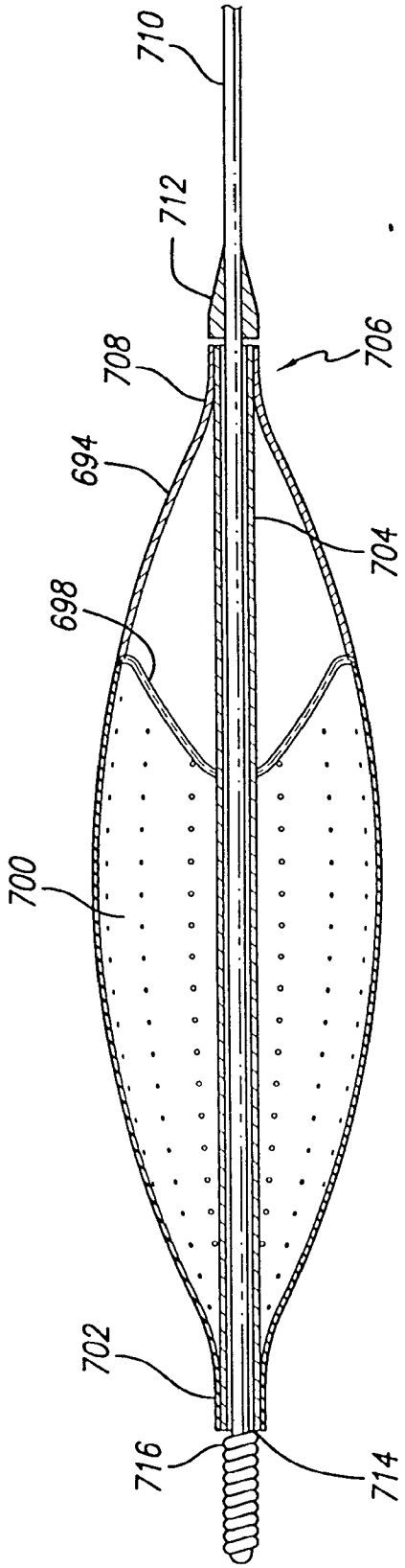
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FIG. 50

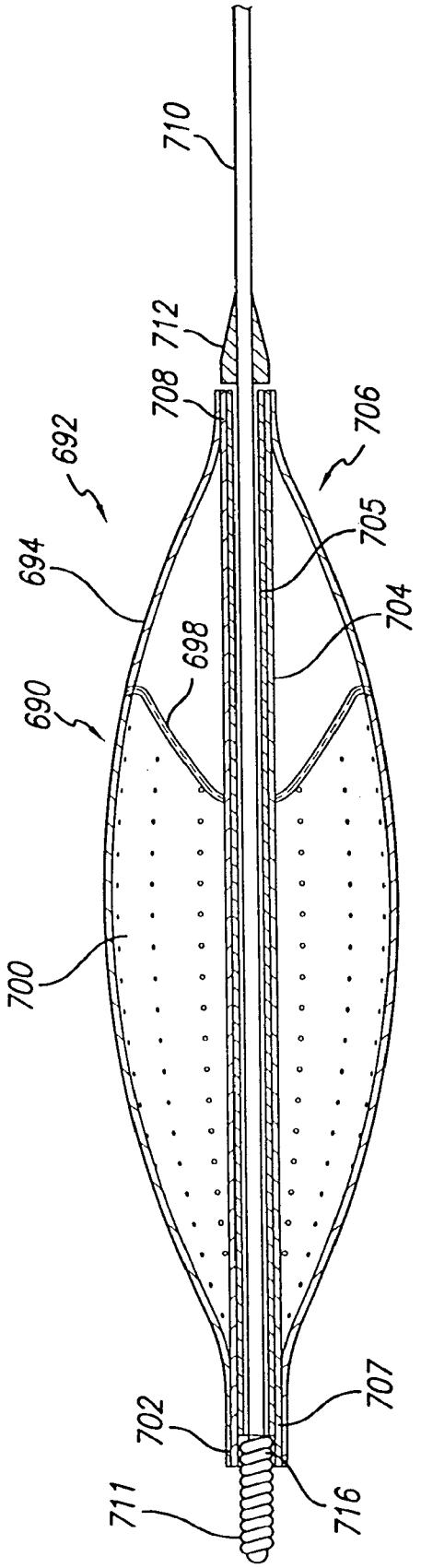

FIG. 51

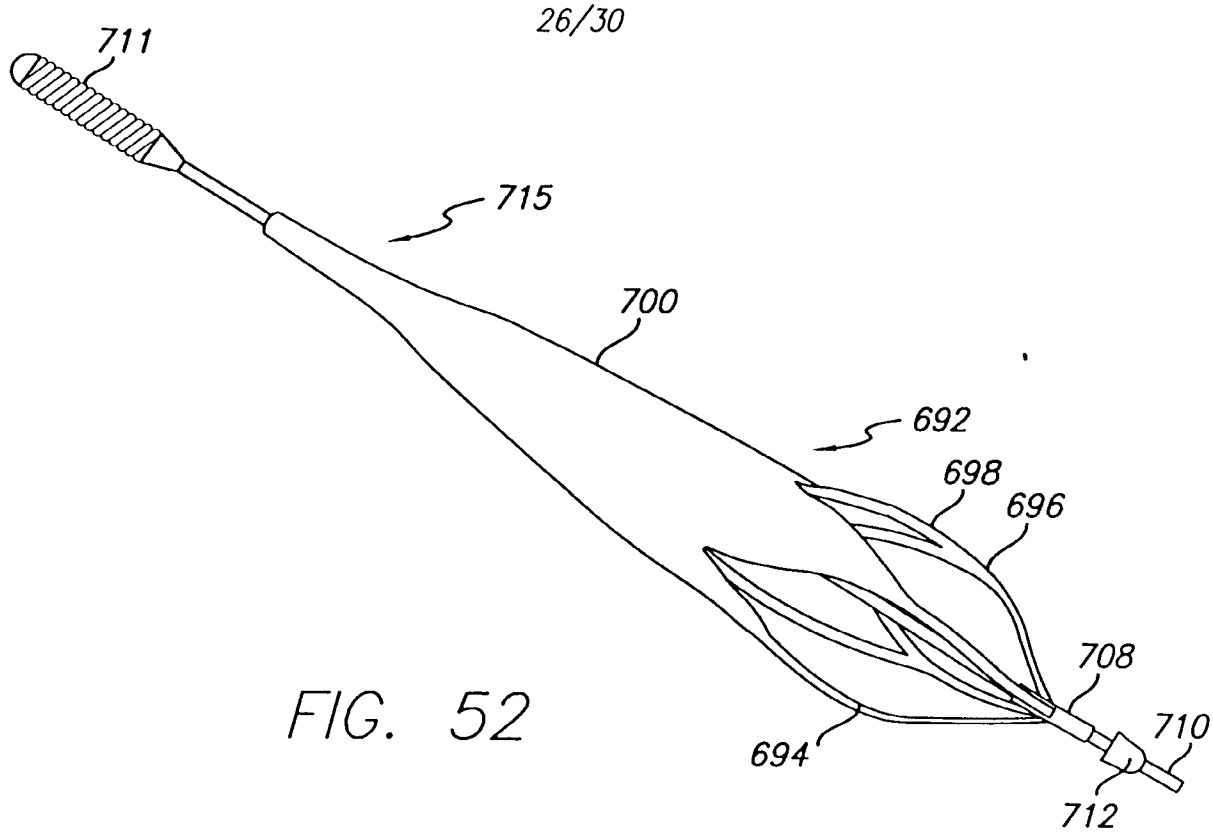

FIG. 52

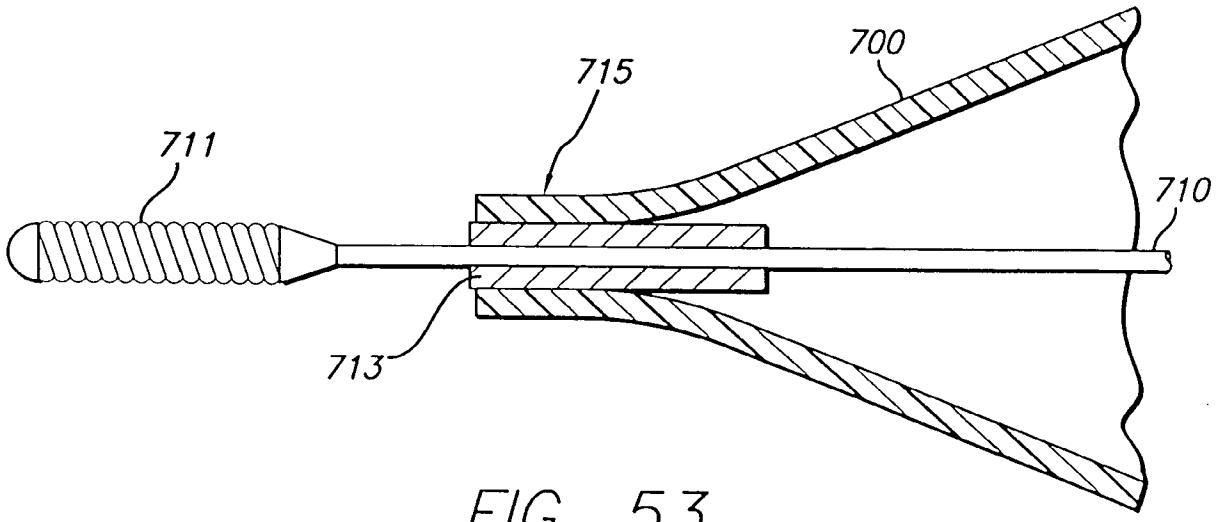

FIG. 53

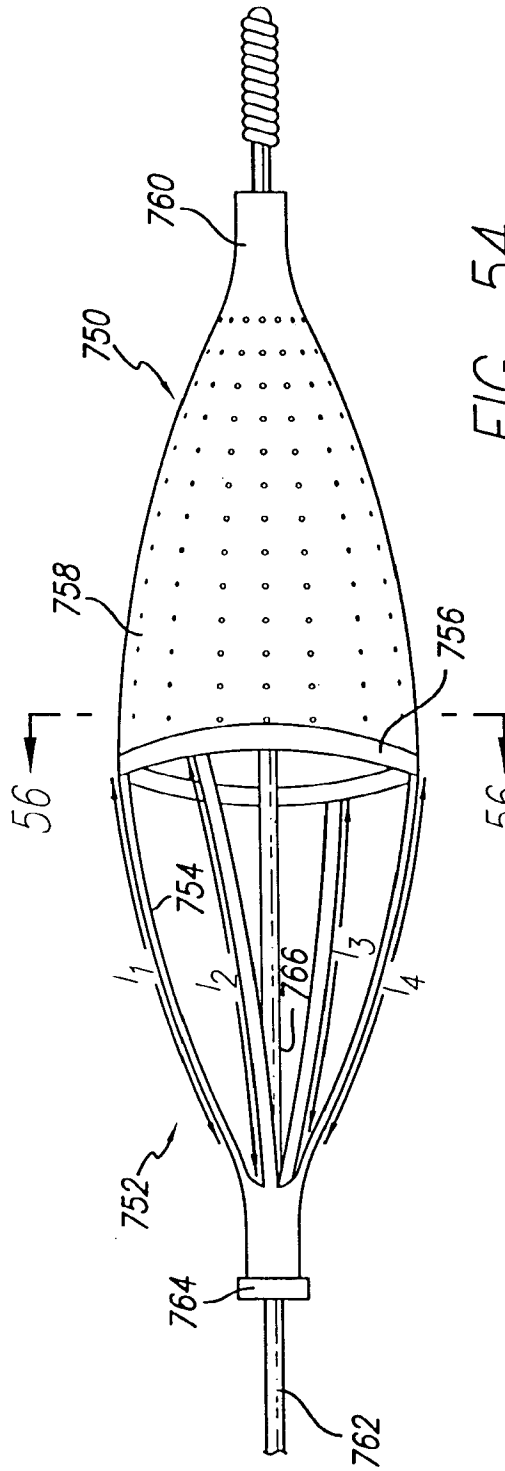

FIG. 54

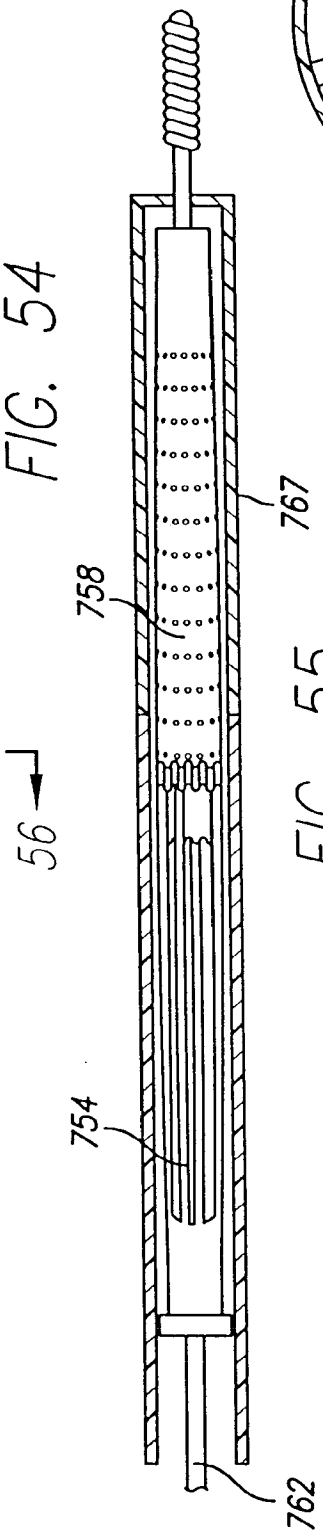

FIG. 55

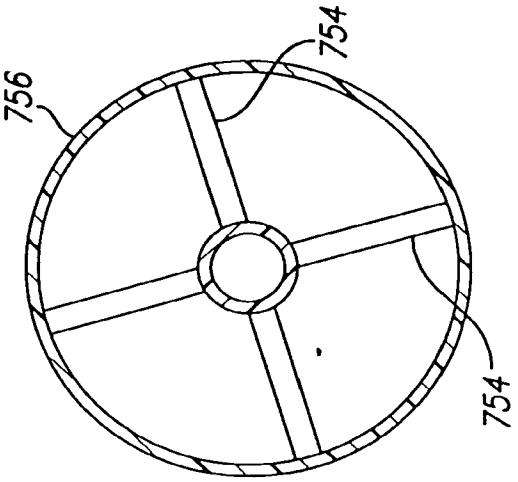

FIG. 56

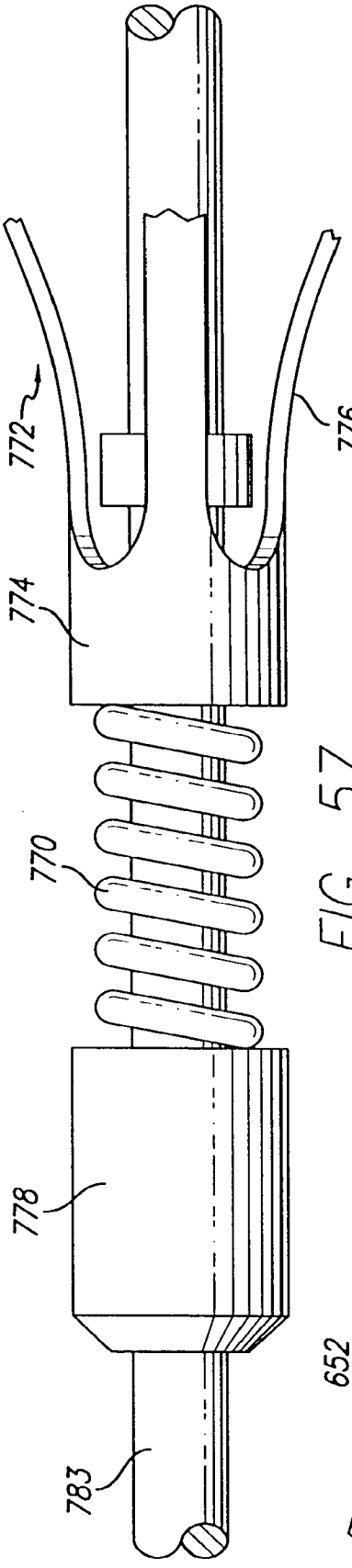

FIG. 57

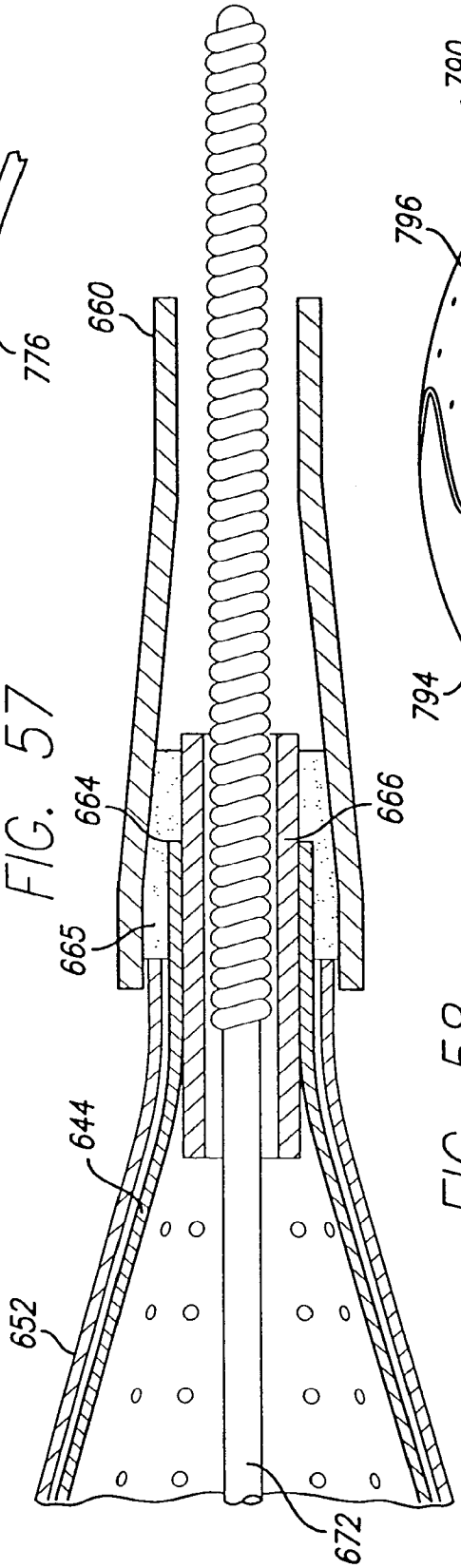

FIG. 58

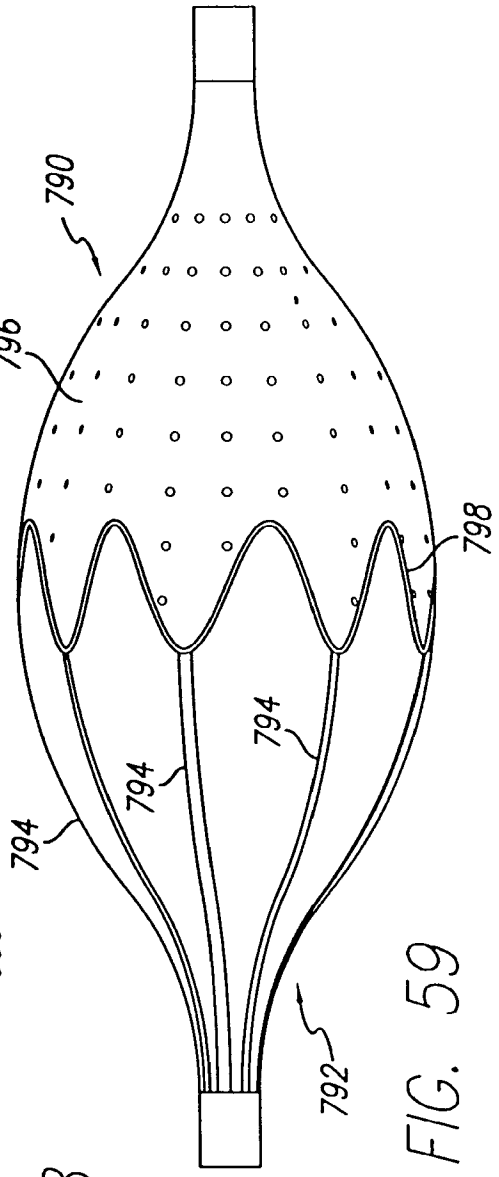

FIG. 59

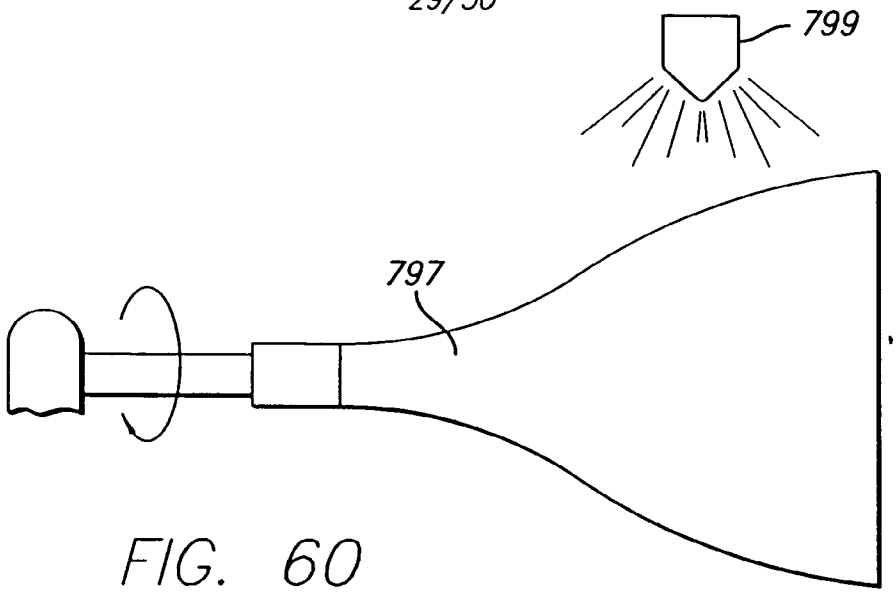

FIG. 60

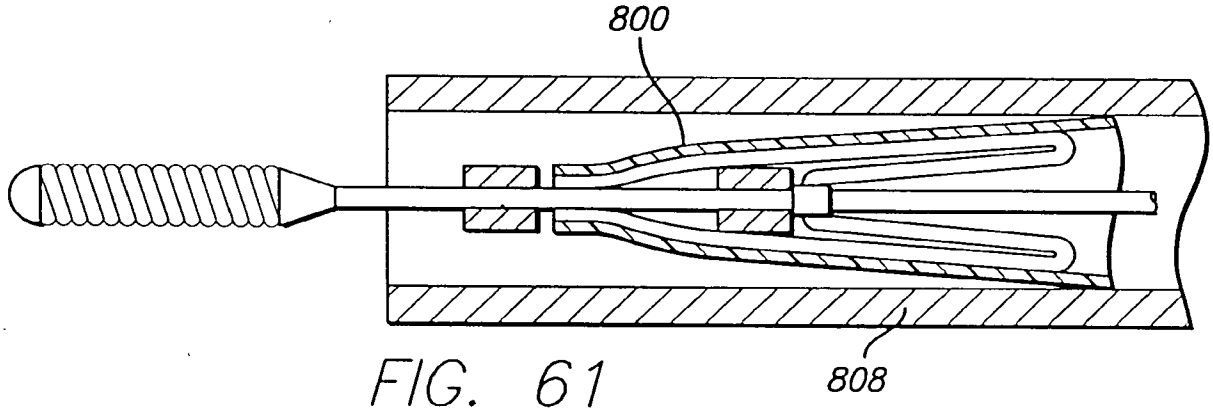

FIG. 61

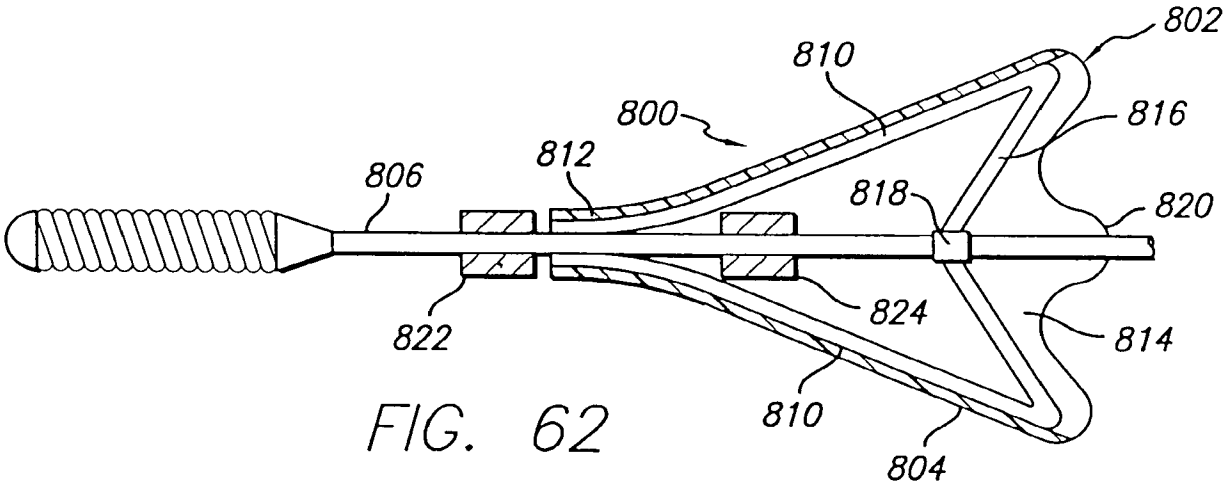

FIG. 62

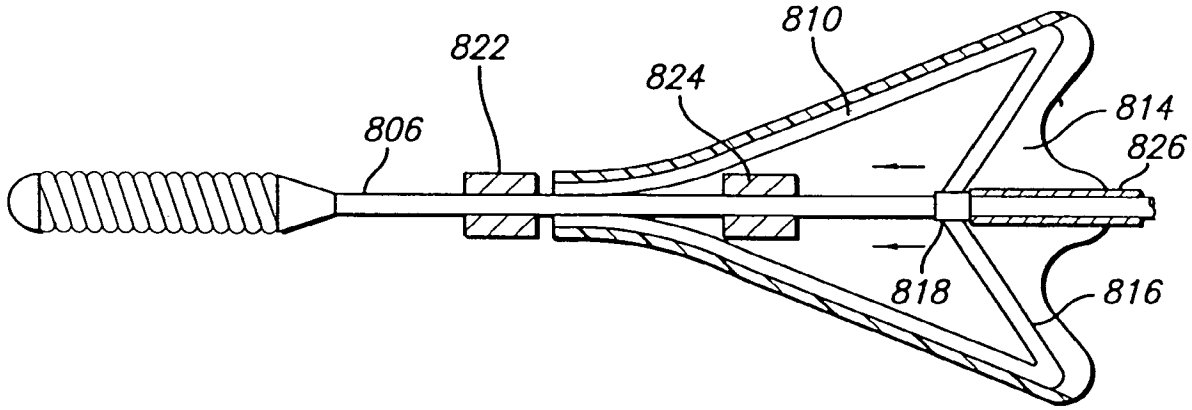

FIG. 63

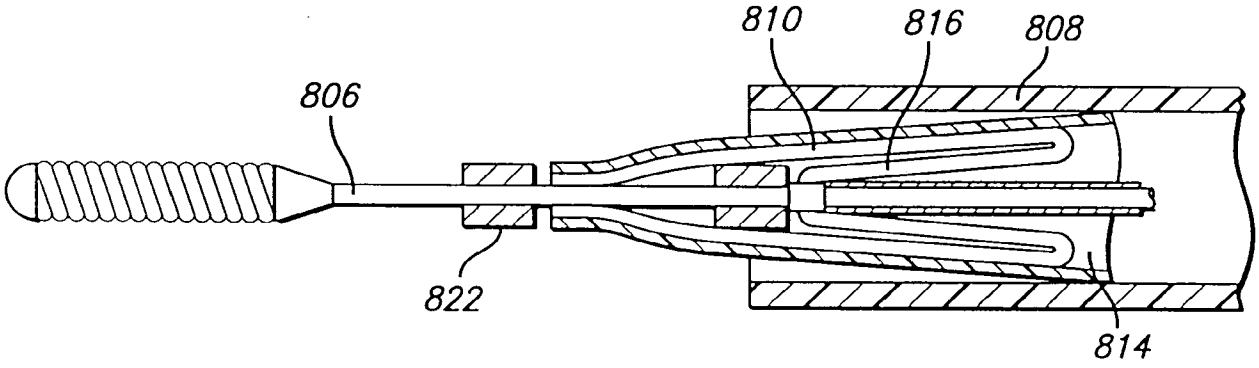

FIG. 64

EXHIBIT C

G1738USD2

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LOS ANGELES

OCT 22 2007

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,490	09/17/2003	John F. Boylan	~~ACS~~ 65471 (2133XXD) ACSES	4845

24201 7590 10/18/2007

THM

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HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
MENDOZA, MICHAEL G	
ART UNIT	**PAPER NUMBER**
3734	
MAIL DATE	**DELIVERY MODE**
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

FINAL REJECTION

2 - MONTH RESPONSE DUE: Dec. 18, 2007
3 - MONTH RESPONSE DUE: Jan. 18, 2008
NOTICE OF APPEAL DUE: _____
(6-MONTH PERIOD ENDS) Apr. 18, 2008

Office Action Summary	Application No.	Applicant(s)	
	10/664,490	BOYLAN ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,32,33 and 36-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 32, 33, 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 4/12/2007 have been fully considered but they are not persuasive. Regarding the arguments to claims 1-4 see drawings.

2. Regarding the arguments to the coating not being proximal. The coating is placed on the external surface of the strut and not on the internal surface. The external surface is proximal to the filter compared to internal surface.

3. Regarding the arguments to the coating only being on areas of low strain, the device of Huter et al. teaches the limitation. Huter et al. teaches coating the struts of the device. The deployment member 22 of Huter et al. is not coated. As disclosed in the specification of the instant application, the struts are the regions of low strain, and the deployment member is the area of high strain (pg. 51, lines 19-24). The device of Huter el al. reads on the limitations.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. 6461370

3. Gray et al. teaches an embolic protection device fro capturing embolic debris released into a body vessel of a patient, comprising: a shaft member having a distal end, a proximal end and a stop fitting; a filtering assembly rotatably mount on the shaft member near the distal end, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly, the filtering assembly being mounted on an outer tubular member which is coaxially disposed over an inner tubular member having a length shorter than the outer tubular member, wherein one end of the inner tubular member is fully capable of abutting against the stop fitting; wherein the shaft member is a guide wire and includes a distal spring tip coil, the spring tip coil serving as the stop fitting; wherein each of the inner and outer tubular members has a proximal end and a distal end and the guide wire includes a second stop fitting in an abutting relationship with the proximal ends of the outer and inner tubular members; and where the outer tubular member extends over a portion of the spring tip coil of the guide wire.

Fig. 2

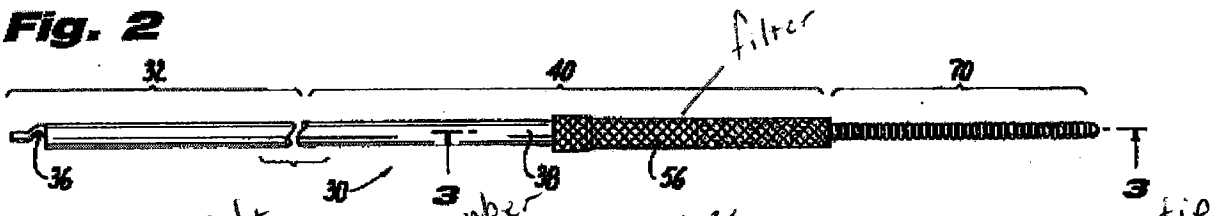
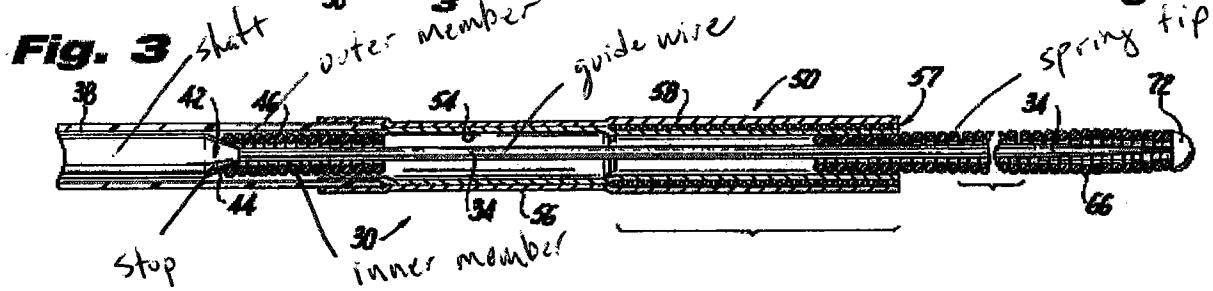


Fig. 3



4. Claims 32, 33, and 36-39, and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Huter et al. 6511496 as evidenced by Bachinski et al. 5800525

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

5. As to claims 32, 33, 38, 41, and 43, Huter et al. teaches an embolic protection device for capturing embolic debris released into the body vessel of a patient, comprising: a shaft member; a filtering element including an expandable strut assembly and a filter attached to the strut assembly; a layer of polymeric material deposited only on portions of the strut assembly proximal to the filter; wherein the polymeric material is selected from the group consisting of PTFE and polyimide; and wherein the expandable strut assembly is made from a material having self-expanding properties (col. 6, lines 36-37).

6. Huter et al. teaches depositing a polymeric material only on the external surface of the strut (col. 7, lines 26-29). The filter is placed on the external surface of the strut. The external surface of the strut is more proximal to the filter than the internal surface of the strut. Therefore, Huter et al. teaches the limitation of only on portions of the strut assembly proximal to the filter.

7. As to claim 39, Huter et al. teaches the embolic protection device of claim 38, wherein the coating substance is a hydrophilic substance. Huter et al. coating with

PTFE. PTFE is a hydrophilic substance as evidenced by Bachinski et al. (col. 3, lines 46-51).

8. As to claims 36, 37, and 42, Huter et al. teaches an embolic protection device for capturing embolic debris release into the body vessel of a patient, comprising: a shaft member; a filtering element including an expandable strut assembly and a filter attached to the strut assembly; the expandable strut assembly having regions which experience high strain and regions which experience low strain; a layer of polymer material deposited only on the regions which experience low strain; wherein the polymeric material is selected from the group consisting of PTFE and polyimide (col. 4, lines 15-37); and wherein the expandable strut assembly is made from a material having self-expanding properties (col. 6, lines 36-37).

9. The specification of the instant application defines the area of high strain to be the deployment member and the area of low strain being the struts (pg. 51, lines 19-24). Huter et al. teaches coating only the struts (col. 7, lines 15-31). Therefore, Huter et al. teaches the limitation of a layer of polymer material deposited only on the regions which experience low strain.

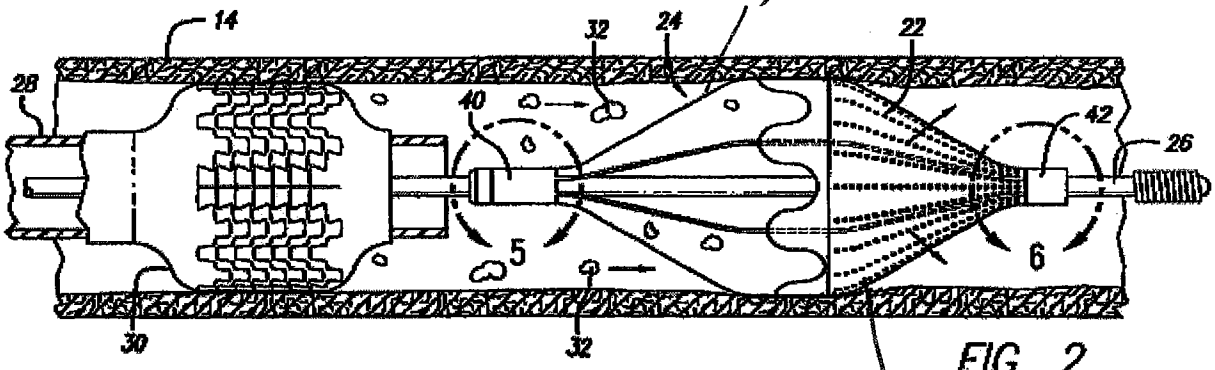


FIG. 2

deployment member / filter (high strain)

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.

12. Gray et al. teaches the embolic protection device of claim 2 except for wherein the outer and inner tubular member are made from polyimide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyimide, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Furthermore, Gray et al. teaches that parts of the device are made from polyimide (col. 3, lines 55-56).

13. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Bachinski et al.

14. Huter et al. teaches the embolic protection device of claim 38. It should be noted that fails to teach wherein the coating substance is heparin. Huter et al. teaches the used of PTFE.

15. Bachinski et al. teaches a device with a common coating of PTFE. Bachinski et al. also teaches an alternative coating of heparin (col. 3, lines 48-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention

was made to use heparin as an obvious alternative to PTFE for providing a smooth biocompatible surface for preventing clotting (col. 3, lines 52-56).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER

EXHIBIT D

US006461370B1

(12) **United States Patent**
Gray et al.

(10) **Patent No.: US 6,461,370 B1**
(45) **Date of Patent: Oct. 8, 2002**

(54) **TEMPORARY VASCULAR FILTER GUIDE WIRE**

(75) Inventors: **William Gray**, Corrales, NM (US); **Richard A. Gambale**, Tyngsboro, MA (US)

(73) Assignee: **C. R. Bard, Inc.**, Murray Hill, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/457,203**

(22) Filed: **Dec. 6, 1999**

Related U.S. Application Data

(63) Continuation of application No. PCT/US98/23516, filed on Nov. 3, 1998.

(51) **Int. Cl.**[7] **A61F 2/01**
(52) **U.S. Cl.** **606/200**
(58) **Field of Search** 606/108, 127, 606/126, 113, 114, 91, 92, 200

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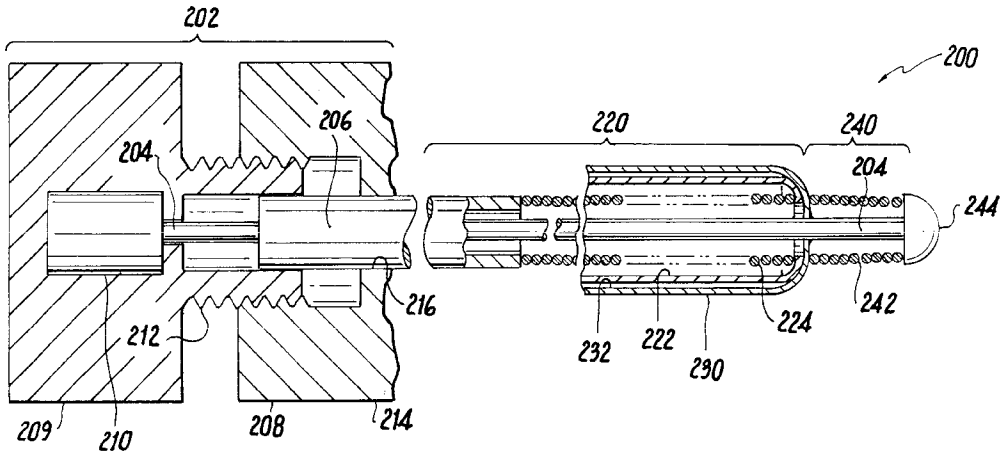
Primary Examiner—Michael H. Thaler
(74) *Attorney, Agent, or Firm*—Darby & Darby

(57) **ABSTRACT**

A vascular filter guide wire is disclosed for directing precision placement of a cur proximate a blood vessel lesion and filtering particulate matter dislodged by treatment of the vessel. The guide wire includes an actuating mechanism, an elongated flexible core wile having a proximal end mounted to the actuating mechanism and a distal end for insertion through a vasculature to a position downstream of the restriction. A tubular flexible shaft is slidably disposed telescopically along the core wire and includes a proximal portion affixed to the actuating mechanism in movable relation to the core wire. The guide wire includes a collapsible filter at its proximal end to the distal portion of the shaft and, at its distal end, to the core wire. The filter deploys radially in response to axial moment of the core wire relative to the shaft so that it can trap particulate matter arising from treatment of the lesion.

14 Claims, 8 Drawing Sheets



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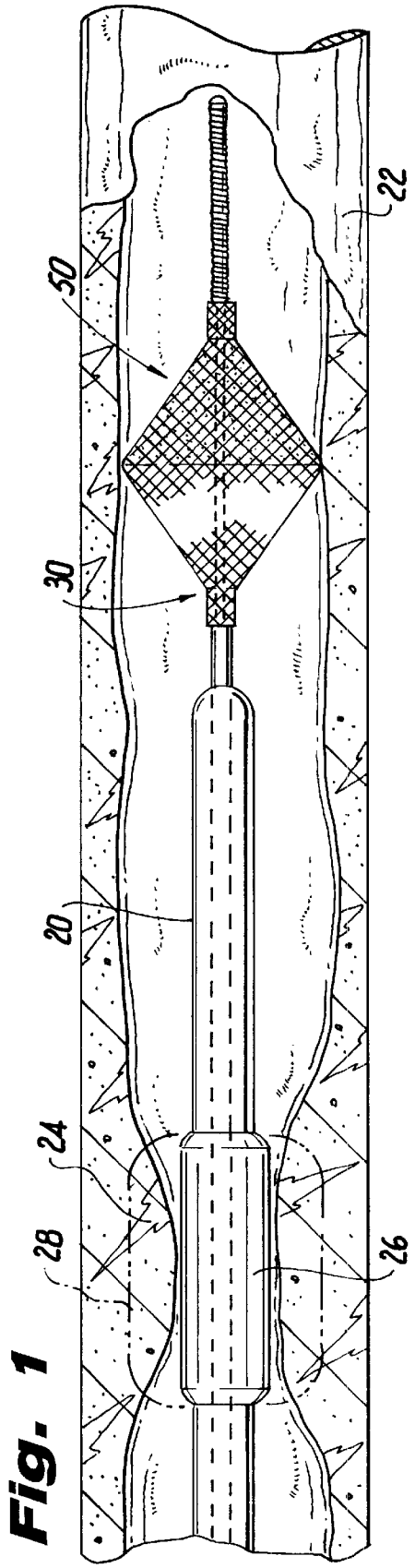


Fig. 1

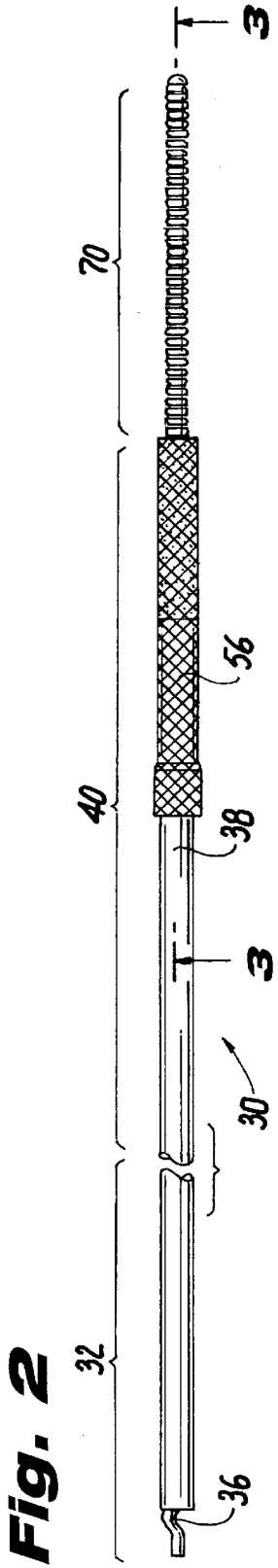


Fig. 2

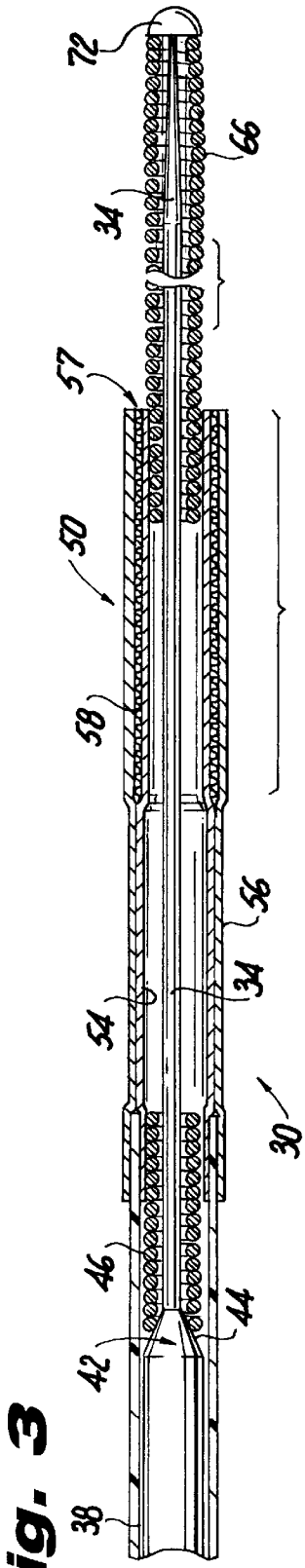


Fig. 3

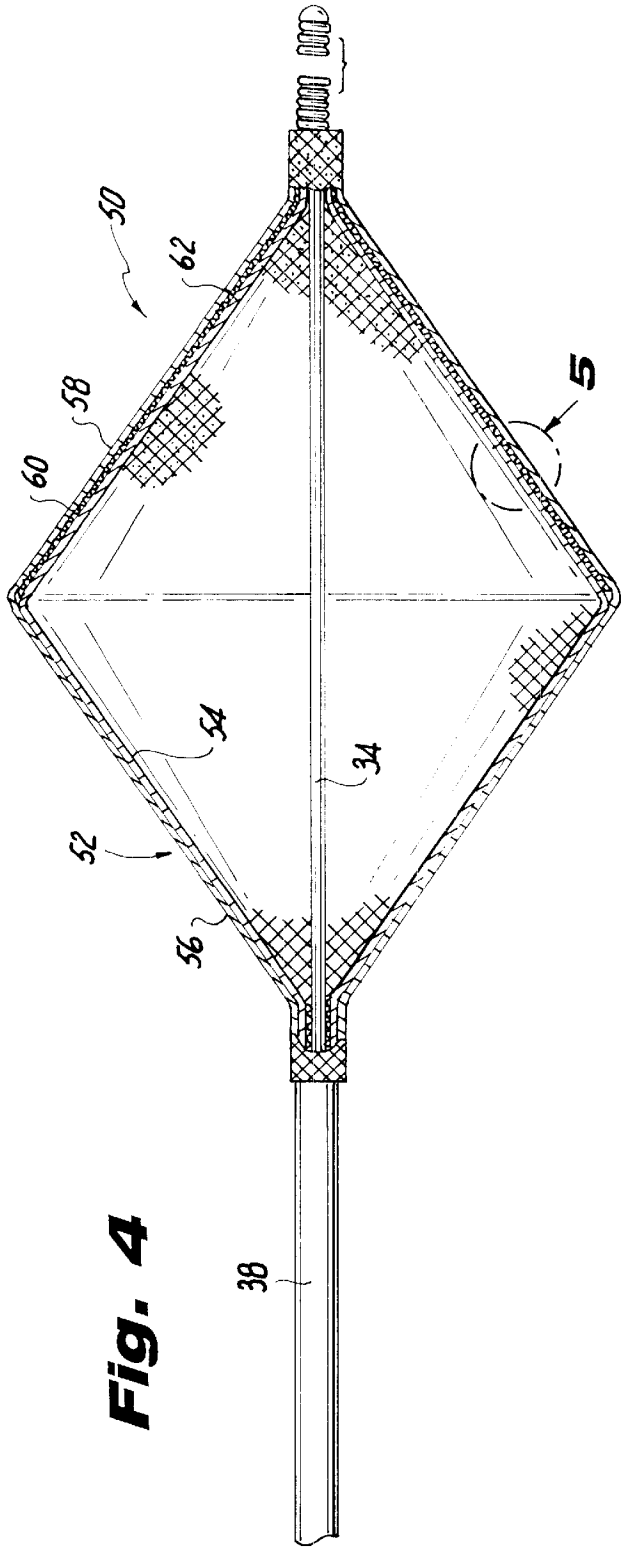


Fig. 4

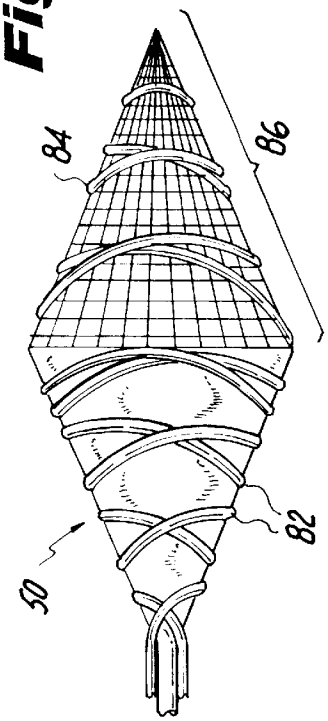


Fig. 6

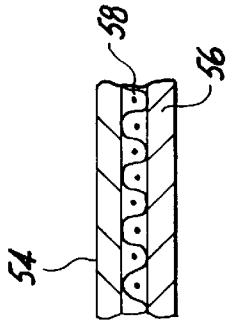


Fig. 5

Fig. 7

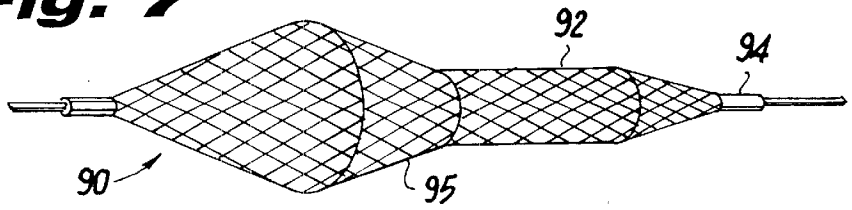


Fig. 7a

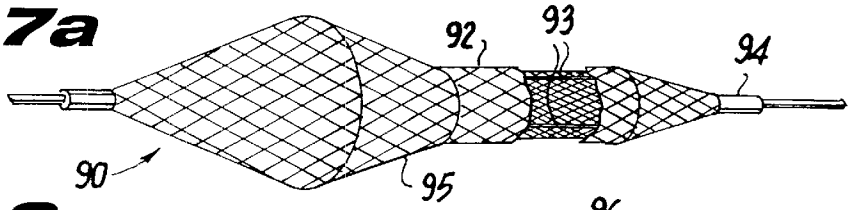


Fig. 8

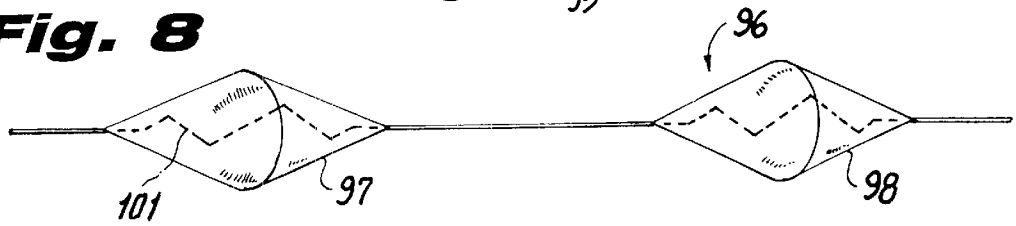
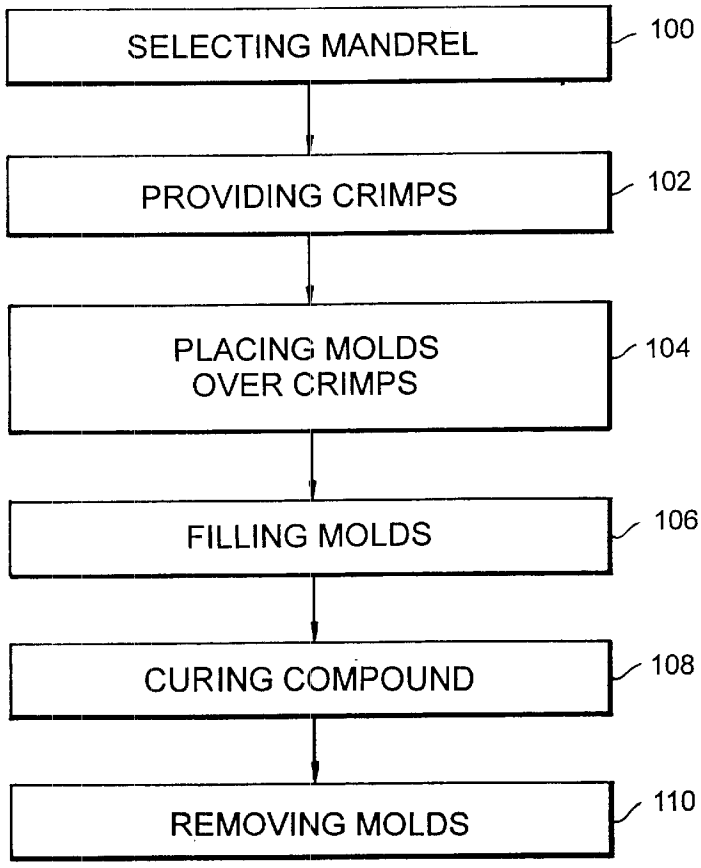


Fig. 9



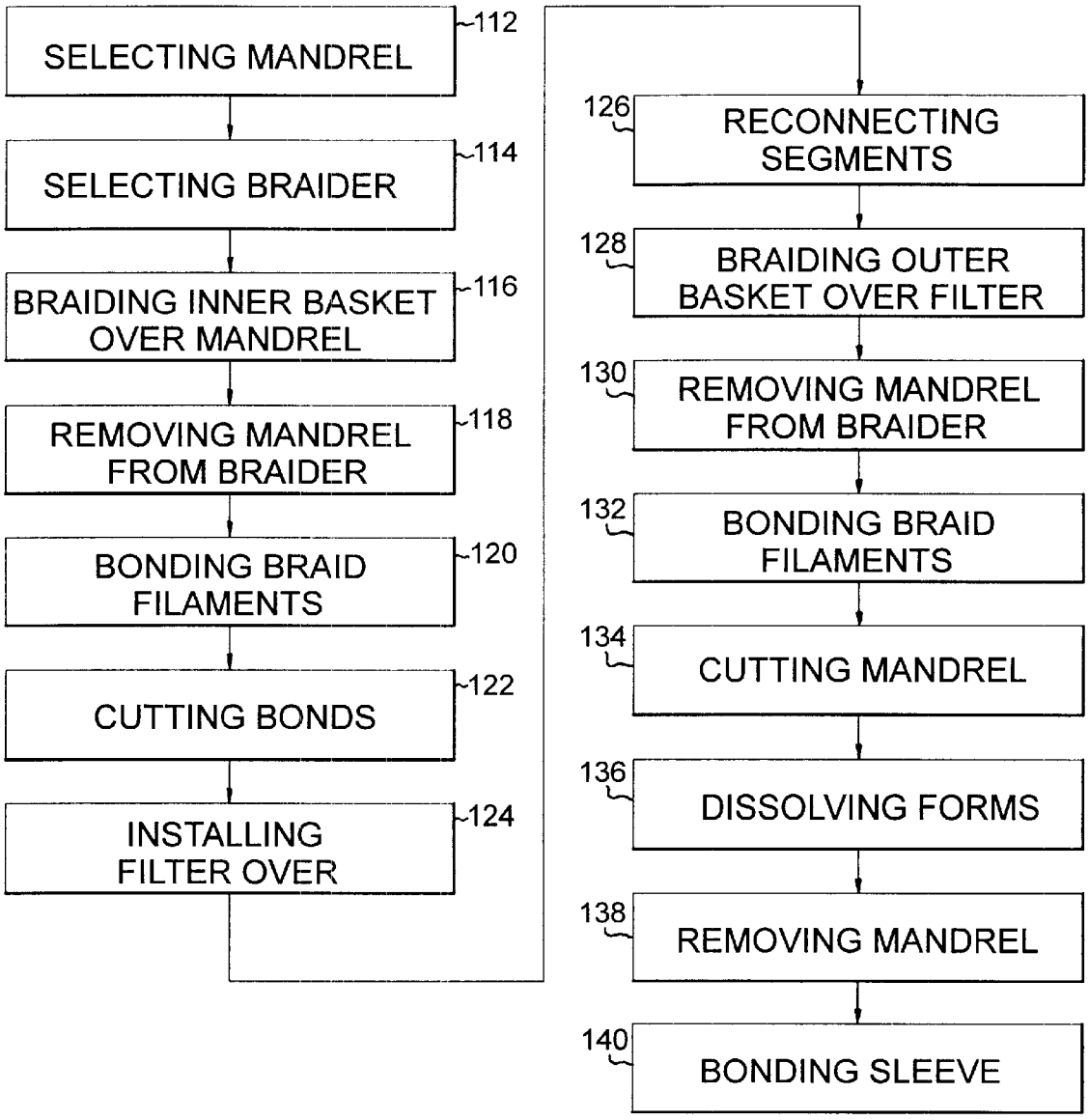

SELECTING MANDREL
112
SELECTING BRAIDER
114
BRAIDING INNER BASKET OVER MANDREL
116
REMOVING MANDREL FROM BRAIDER
118
BONDING BRAID FILAMENTS
120
CUTTING BONDS
122
INSTALLING FILTER OVER
124
126
RECONNECTING SEGMENTS
128
BRAIDING OUTER BASKET OVER FILTER
130
REMOVING MANDREL FROM BRAIDER
132
BONDING BRAID FILAMENTS
134
CUTTING MANDREL
136
DISSOLVING FORMS
138
REMOVING MANDREL
140
BONDING SLEEVE

Fig. 10

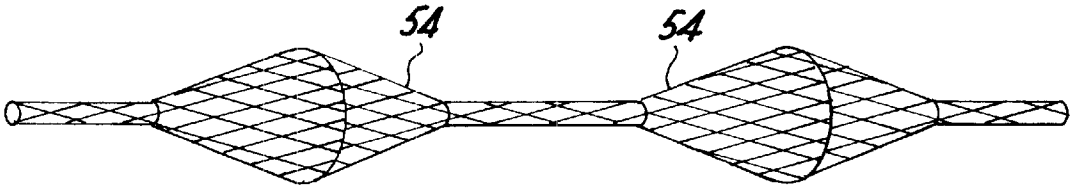


Fig. 11a

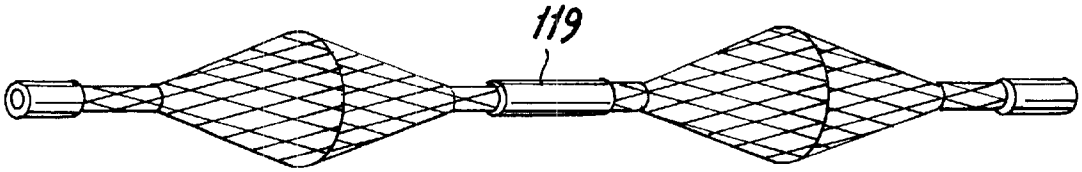


Fig. 11b

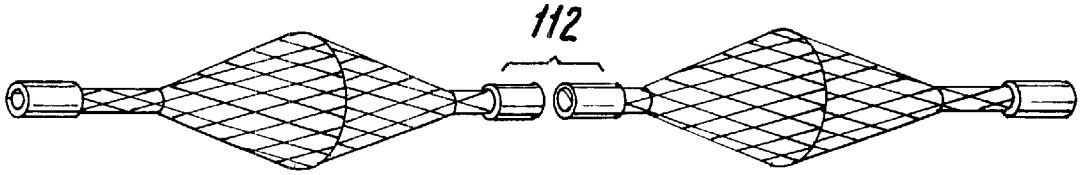


Fig. 11c

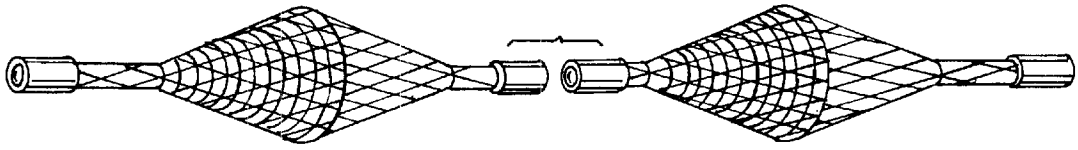


Fig. 11d

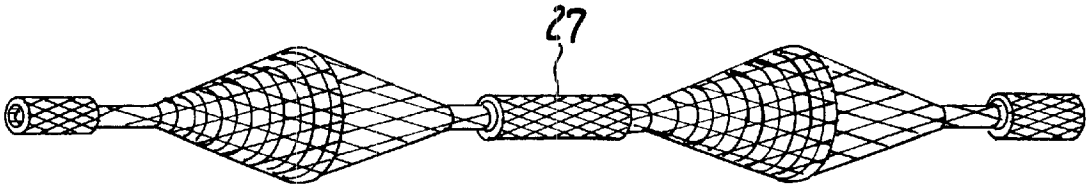


Fig. 11e

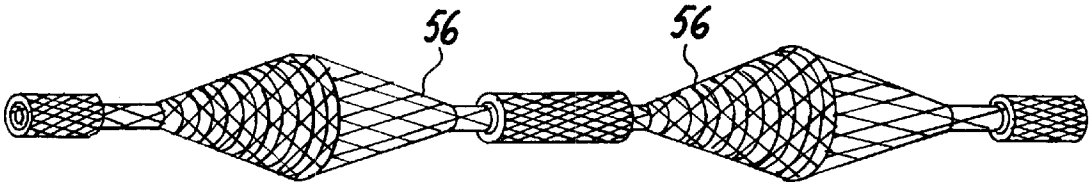


Fig. 11f

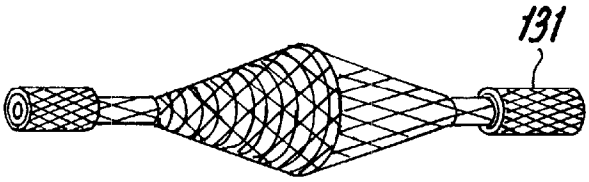


Fig. 11g

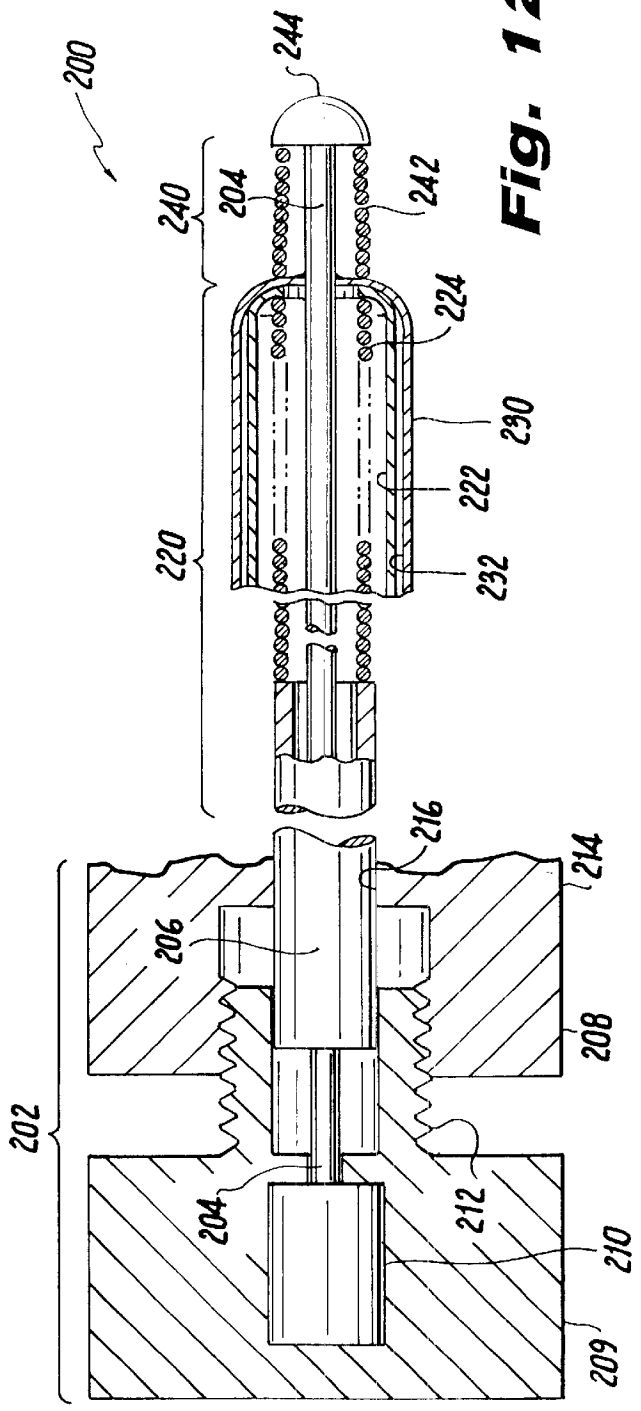


Fig. 12

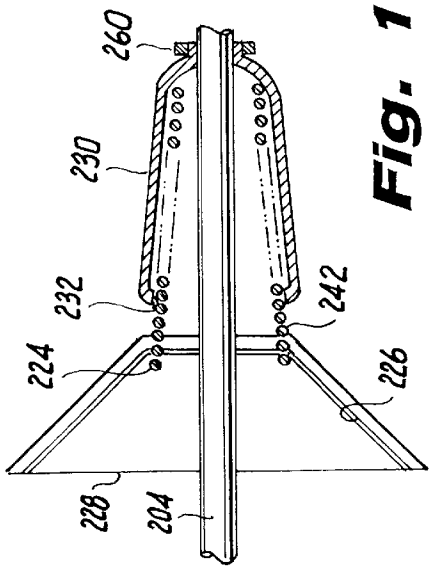


Fig. 13a

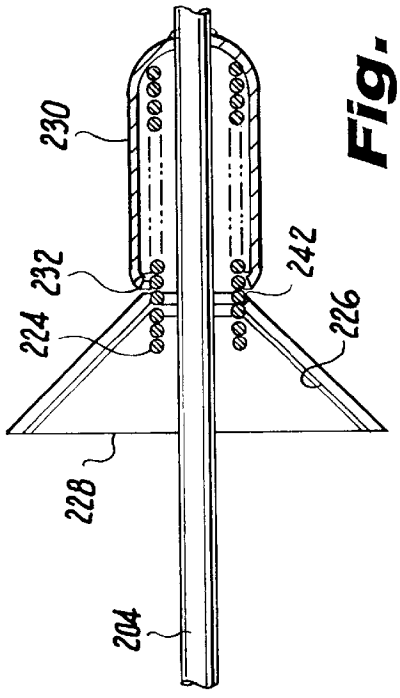


Fig. 13

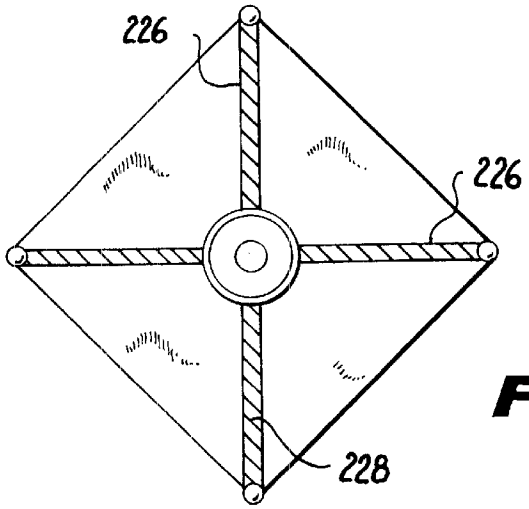


Fig. 14

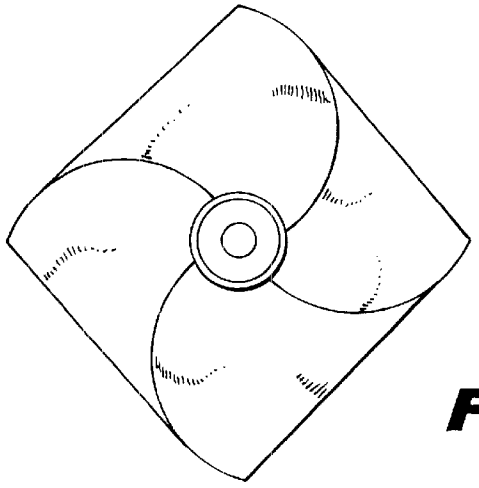


Fig. 15

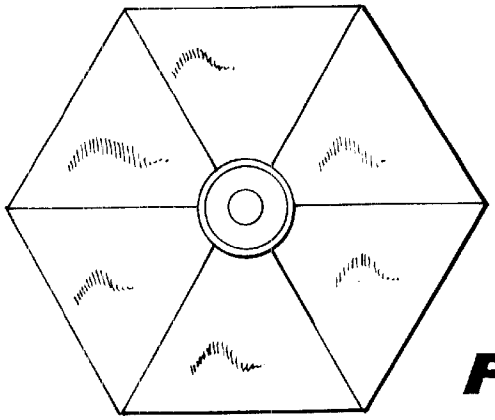


Fig. 16

TEMPORARY VASCULAR FILTER GUIDE WIRE

This is a continuation of International Application Ser. No. PCT/US98/23516, filed Nov. 3, 1998.

FIELD OF THE INVENTION

The invention relates to vascular filters intended to capture embolic particles, by means of filtration, that may arise from the treatment of diseased blood vessels.

BACKGROUND OF THE INVENTION

Percutaneous intravascular treatment of diseased blood vessels, such as angioplasty or stent placement procedures, may result in the dislodgment of loose plaque or thrombus which then migrate downstream. Since any such particles may become lodged in other vessels, effectively preventing blood from passing into a the organ which that vessel supplies, and potentially causing serious end-organ damage which may be difficult or impossible to reverse, effective avoidance of this complication is extremely important.

One of the early methods of removing residual matter resulting from an angioplasty procedure using a balloon catheter involved maintaining the balloon in an inflated state while performing the intended intervention on the blood vessel. In this manner, much of the material could be removed without an extraneous filtering device. However, the reliability of such a procedure, especially for blood vessels supplying oxygen to the brain, necessitated substantial improvement.

Previous attempts at vascular filters have included a vena caval filter, which is permanently deployed in the vena cava via a peripheral vein in order to prevent embolisation of blood clots from the veins of the legs to the lungs, thus avoiding potentially serious and life threatening pulmonary embolism. The filter typically included a plurality of anchoring legs bent outwardly to form hooks to penetrate the vessel wall and secure the filter permanently in position. An example of such a device is disclosed in U.S. Pat. No. 4,619,246.

While conventional vena caval filters work well for their intended purposes, they suffer from the disadvantages associated with damaging the inner vessel wall through the inherent penetrating nature of the hooks, and blockage caused over time as the filter becomes endothelialized with the blood vessel inner wall or as recurrent blood clots obstruct blood flow through the filter.

In an effort to resolve the problems with vena caval filters, those skilled in the art have developed temporary filtering mechanisms that attach to an angioplasty catheter and withdraw from the vasculature following the procedure. One proposal, disclosed in U.S. Pat. No. 4,723,549, discloses a collapsible wire mesh filter disposed around the distal portion of a wire guided balloon catheter. A filter balloon is positioned beneath the wire mesh and inflates radially outwardly to expand the wire mesh when inserted downstream of a stenosed blood vessel. As the vessel is treated, fine particles dislodged from the stenosis are trapped by the mesh and subsequently removed with the filter and catheter following the procedure.

A similar device and method, disclosed in U.S. Pat. No. 4,873,978 includes a balloon catheter directed through a vasculature by a guide wire. The catheter mounts a strainer at its distal end that responds to actuation of a separate control wire to open and close a plurality of tines capable of retaining dislodged particles from a treated stenosis.

The temporary filter devices described above require additional lumens and/or control wires beyond those associated with the catheter guide wire to control the filtering procedure. The extra lines and wires typically create added complexity for the operator. Moreover, it is often desirable to adjust the relative spacing between the deployed filter and the stenosed area due to the potential presence of additional blood vessels proximate the stenosis. Because the conventional filters are mounted to the distal ends of the respective catheters, adjustments during the procedure typically cannot be made. Furthermore, the use of balloon catheters and stent devices involving the same procedure could not be achieved with filter protection in place.

Therefore, a need exists in the art for a temporary vascular filter which does not require additional control wires and catheter lumens. Moreover, the need exists for such a filter in which adjustment of the filter with respect to a lesioned vessel area, and allows for the exchange of various types of devices (e.g., balloon catheters, stents, etc.), while maintaining protection against distal emboli. The temporary vascular filter guide wire of the present invention satisfies these needs.

SUMMARY OF THE INVENTION

The apparatus and method of the present invention minimizes the complexity associated with manipulating a vascular filter during an angioplasty or stent placement procedure by incorporating the filter on a catheter guide wire such that the guide wire performs the dual functions of guiding the catheter to a stenosed location, and filtering dislodged particles flowing downstream of the treated area. Moreover, because the guide wire operates independently of the catheter, relative spacing between the filter and the lesion location may be easily altered, and exchanges of various devices over the wire are possible.

To realize the advantages described above, the invention, in one form, comprises a vascular filter guide wire for directing precision placement of a catheter or stent proximate a lesion and selectively filtering particulate debris dislodged by treatment. The guide wire includes an actuating mechanism and an elongated flexible core wire having a proximal end mounted to the actuating mechanism and a distal end for insertion through a vasculature to a position downstream of the lesion. A tubular flexible shaft is slidably disposed telescopically along the core wire. The shaft includes a proximal portion affixed to the actuating mechanism in movable relation to the wire proximal end, and a distal portion disposed inwardly from the core wire distal end for placement downstream of the lesion. A collapsible strainer coupled to the shaft distal portion is operable, in response to relative displacement between the shaft and the core wire, to radially extend outwardly within the vasculature so that it can trap particulate matter arising from the treatment of the lesion.

In another form, the invention comprises a catheter system for treating a lesion within the vasculature. The catheter system includes a catheter having a lesion treatment device and a vascular filter guide wire for directing the catheter to the lesion. The guide wire includes a collapsible filter for deployment downstream of the catheter to trap particulate matter dislodged from the lesion during the treatment.

In yet another form, the invention comprises a method of filtering particulate debris from a vasculature caused by treatment of a lesion with a catheter having a lesion treatment portion, the catheter being guided to the location of the lesion by a vascular filter guide wire having a core wire, a

slidable shaft, and a collapsible filter mounted on the shaft and deployable upon relative displacement between the core wire and the shaft. The method includes the steps of first guiding the vascular filter guide wire through the vasculature along a predetermined path to a lesion such that the filter is disposed downstream of the lesion. The next step involves deploying the filter radially outwardly by shifting the shaft relative to the core wire. Then, the catheter is run over the guide wire along the predetermined path to position the lesion treatment portion of the catheter proximate the lesion. The method continues by treating the lesion according to a predetermined procedure then maintaining the filter in a deployed position until the risk of particulate matter is substantially eliminated. The catheter is then withdrawn from the vasculature and the filter retracted radially inwardly by shifting the shaft back to the original position. The method then concludes with the step of removing the guide wire from the vasculature.

One embodiment of the invention comprises a vascular filter for controllably expanding within a blood vessel to trap particulate matter loosened from treatment of a lesion. The filter is responsive to relatively shiftable control elements to expand and retract and includes a braid comprising a composite metallic/polymeric material. The material includes a plurality of metallic filaments mounted to the respective shiftable shaft and core wire to define a support structure and a polymeric mesh interwoven with the metallic filaments to define a strainer.

Another form of the invention comprises a method of fabricating a vascular filter. The method includes the steps of first selecting a mandrel having a plurality of consecutively connected forms and weaving a continuous layer of braid over the consecutively connected forms. The method proceeds by bonding the braid filaments at spaced apart sections between respective forms and separating the respective braided forms at the bonded sections. The forms are then removed from the layer of braid.

Other features and advantages of the present invention will be apparent from the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an enlarged, partial sectional view of a catheter system of the present invention deployed within a blood vessel;

FIG. **2** is a partial longitudinal view of a guide wire in a retracted position according to a first embodiment of the present invention;

FIG. **3** is a partial longitudinal sectional view along line **3**—**3** of FIG. **2**;

FIG. **4** is a partial longitudinal sectional view similar to FIG. **3** but in a deployed orientation;

FIG. **5** is an enlarged view of detail **5**—**5**;

FIG. **6** is a longitudinal view of a filter construction according to an alternative embodiment of the present invention;

FIG. **7** is a longitudinal view of a filter construction according to yet another embodiment of the present invention;

FIG. **7***a* is a cut-away portion of the FIG. **7** filter construction which illustrates longitudinal pleats, according to the FIG. **7** embodiment of the present invention;

FIG. **8** is a mandrel system for use in the method of the present invention;

FIG. **9** is a block diagram illustrating steps in preparing the mandrel of FIG. **8**;

FIG. **10** is a block diagram illustrating steps in fabricating the filter of the present invention;

FIGS. **11***a*–**11***g* are views of various stages of construction corresponding to the steps of FIG. **10**;

FIG. **12** is a partial longitudinal sectional view of a guide wire in a retracted state according to a second embodiment of the present invention;

FIG. **13** is a partial view of the guide wire of FIG. **12** in an extended state;

FIG. **13***a* is an alternative embodiment of the FIG. **13** which is frusto-conical in shape, according to an alternative embodiment of the present invention;

FIG. **14** is an axial view along line **14**—**14** of FIG. **13**;

FIG. **15** is an axial view similar to FIG. **14** and showing an alternative strut arrangement; and

FIG. **16** is an axial view similar to FIG. **14** and showing an alternative strut arrangement.

DETAILED DESCRIPTION OF THE INVENTION

With reference to FIG. **1**, percutaneous angioplasty or stent placement techniques enable operators to minimize trauma often associated with more invasive surgical techniques. This is possible through the use of a thin catheter **20** that advances through the vascular system to a predetermined blood vessel **22** having a lesion such as a stenosis **24** blocking the flow of blood therethrough. Typically, the catheter includes a lesion treatment device such as a balloon **26** or stent (not shown) for positioning coaxially within the lesion. Once positioned, the balloon or stent radially expands, as shown at **28**, to exert a radially outwardly directed force against the material and initiate dilation thereof.

In order to reach the lesioned area, however, the catheter must be able to follow a trackable path defined by a catheter guide wire. In accordance with a first embodiment of the present invention, a catheter guide wire, generally designated **30**, provides a trackable path for a catheter and includes a distally disposed collapsible filter **50** to trap particulate matter dislodged by the catheter **20** during treatment of the stenosis.

Referring now to FIGS. **2** through **5**, the guide wire **30** includes a proximal section **32** comprising a solid core wire **34** having a wave-shaped proximal end **36** (FIG. **2**). A tubular shaft **38** is coaxially disposed around the core wire and includes an outer diameter equal to the nominal size of the guide wire. The inner diameter of the tube is sized to form a friction fit with the core wire proximal end when slid thereover during insertion and removal of the guide wire. The shaft functions to deploy and retract the filter device, and to guide and support the catheter **20**, and to smoothly transmit rotation from the proximal section **32** to an intermediate section **40**. Preferably, the shaft comprises a polyimide tube or hypotube. In some applications, where relatively long lengths are required, an extension (not shown) may be attached to the proximal section to increase the length up to three meters.

The intermediate section **40** extends axially from the proximal section **32** and generally comprises an extension of the shaft **38** to coaxially surround the core wire **34**. The core wire is formed distally with a primary tapered portion **42** defining an annular shoulder **44** for mounting a coiled spring **46**.

With further reference to FIGS. **2** through **5**, the filter **50** comprises a braided basket **52** having respective inner and

outer braid layers **54** and **56** (FIG. **5**) that, in one embodiment, serve as supports for a fine filter mesh **58**. The supports expand the basket radially outwardly with the filter axial ends compressed inwardly, and radially retract the basket with the ends tensioned outwardly. The fine mesh **58** (FIG. **5**) is interposed between the inner and outer supports along a distal-half portion **60** of the basket to prevent particulate matter from flowing through the blood vessel downstream of the treated stenosis. It is contemplated that the size of the pores of mesh **58** may be in the range of 40 to 500 microns. The meshed distal-half of the filter forms a collection cavity **62** for the material such that when retracted, the material is prevented from escaping the filter.

The proximal end of the filter basket is bonded (e.g. adhesively or by soldering) to the shaft **38** which may be inserted between braid layers **54** and **56**.

The distal extremity **57** of basket abuts a flexible **30** coil spring **66** that coaxially surrounds the tip of the core wire **34**. The guide wire distal tip is tapered and terminates in a hemispherically shaped tip **72** which is also bonded (e.g. by soldering) to the tip. The guide wire distal tip may be preformed into a "J" configuration (not shown) to aid in advancing the guide wire **30** through the vasculature.

With particular reference to FIG. **6**, the preferred embodiment of filter **50** according to the present invention includes a braid comprising a composite metallic/polymeric material, eliminating the necessity of a separate mesh layer. In such an embodiment, a plurality of metallic filaments **82** provide structural support to the assembly for deploying and collapsing the filter. Polymeric filaments **84** are located on the distal half of the braid only, to provide a filtration cone **86**. The dual materials, braided simultaneously, provide a pic density which will result in filtration spacing of approximately 40 to 500 microns for filtration, at a metal to polymeric ratio of approximately 1:4.

In yet another embodiment of a filter according to the present invention, generally designated **90** and illustrated in FIG. **7**, the filtering medium is wrapped in a cylinder **92** with a closed distal end **94** and a flared proximal end **95**. Flaring of the proximal end may be effected by applying heat and pressure to the material thereby increasing the surface area and causing the material to bow radially outwardly. The cylinder is formed with longitudinal pleats **93** (shown in FIG. **7***a*) that are more flexible and collapsible than a straight cone configuration.

Referring now to FIGS. **8** and **9**, fabrication of the filter **50** may be performed in accordance with a series of process steps as described below. Initially, a mandrel **96** (FIG. **8**) with a series of molded forms **97** and **98** is prepared by selecting a mandrel of appropriate length, at step **100** (FIG. **9**), and providing a plurality of crimps **101** (FIG. **8**) on the mandrel at intervals of approximately two to three inches, at step **102**. The process proceeds by placing molds over the crimps, at step **104**, filling the molds with a dissolvable compound, at step **106**, curing the compound, at step **108**, and removing the molds, at step **110**. Suitable materials for molding include water soluble plastics such as polyethylene oxide, chemical soluble plastics such as styrene or PVC, and other water soluble materials such as sugar cubes, or gypsum based compounds. Molded forms may be continuously fabricated along the length of the crimped mandrel sections to maximize production efficiency. Another suitable method envisioned is to individually form the molds and bond to straight mandrels.

Referring now to FIGS. **10** and **11***a–g*, following preparation of the mandrel **96**, the mandrel itself is selected for the method of fabricating the filters, at step **112**. The method progresses by selecting a braider, at step **114**, and braiding the inner layer **54** (FIG. **11***a*), at step **116**, over the mandrel form system. Because of the convenient serially connected system of forms on the mandrel, the braider progressively weaves a continuous layer of braid over the consecutively connected forms. After the braid is applied, the mandrel is removed from the braider, at step **118**, so that a curable epoxy may be applied to define an adhesive joint **119** (FIG. **11***b*) along spaced apart sections of the braid between forms. This step bonds braid filaments together, at step **120**, so that subsequent separation of the forms minimizes deformation of the braid.

A center section **121** (FIG. **11***c*) of each braid is then cut, at step **122**, and a prefabricated filter **123** (FIG. **11***d*) installed over one side of each form, at step **124**. The individual segments are then reconnected, at step **126**, by splicing a section of heat shrink tubing **127** (FIG. **11***e*) over each severed joint.

After the segments are re-connected, the mandrel assembly is then re-installed into the braider for braiding of the outer basket **56** (FIG. **11***f*), at step **128**. Following braiding, the mandrel is removed from the braider, at step **130**, with the braid filaments bonded together to form a joint **131** (FIG. **11***g*), at step **132**. The mandrel is then cut at approximately one millimeter on the outside end of the adhesive, at step **134**. At this point, the molded form may be dissolved by an appropriate solvent, at step **136**, and the mandrel removed, at step **138**. Lastly, a polyimide sleeve is bonded, at step **140**, to the end opposite the filter.

The alternative filter embodiment **80** may be fabricated similar to the procedure above with only minor variations. Conveniently, because of the composite nature and relatively high pic density of the metallic/polymeric braid, only one braiding step is required. After the final braid, the polymeric strands at the proximal end are mechanically or thermally cut away, and the filaments fused at the large diameter of the formed cone to form the collection cavity and to allow for greater blood flow.

In operation, the guide wire **30** may be advanced through a vascular system in any conventional manner to establish a path for the catheter to track over. Generally, as shown in FIG. **1**, the guide wire is inserted through the lesion and disposed downstream of the lesion **24** a variably selected distance. The distance selected by the operator may be conveniently adjusted merely by further advancing or slightly withdrawing the guide wire. This provides the highly desirable capability of enabling the operator to independently adjust the selected distance to preclude the possibility of embolic material progressing through a branch path between the lesion and the filter. The catheter **20** is then inserted along the guide wire to access the treatment area. Typically, image scanning techniques aid in the exact positioning of the catheter relative to the lesion such that the lesion treatment device will have maximum effectiveness.

The filter may then be deployed by actuating an actuating mechanism (not shown) coupled to the core wire **34** for axially moving the shaft **38** relative to the core wire. As the shaft advances axially along the core wire in the distal direction, the filter basket **52**, having its distal end **57** attached to the fixed core wire and its proximal end connected to the shaft, compresses axially and expands radially outwardly against the inner walls of the blood vessel. In its expanded state, the filter **50** collects any plaque that may have loosened and become dislodged from the treated area.

Once the treatment concludes, and the catheter is withdrawn from the body, the filter is retracted radially inwardly

by shifting the shaft back to its original position. As the filter retracts, the collection cavity **62** traps any material strained against the filter layer. The guide wire itself is then carefully withdrawn from the vasculature.

Referring now to FIGS. **12** through **16**, a temporary filter guide wire according to a further embodiment of the present invention is shown, and generally designated **200**. The guide wire generally includes a proximal end **202** having an actuating mechanism **208**, an intermediate portion **220** including a housed collapsible filter element **222**, and a flexible distal end **240**.

With particular reference to FIG. **12**, the proximal end **202** includes a solid stainless steel core wire **204** having a diameter, for example, of approximately 0.0075 inches and slidably confined coaxially by an elongated shaft **206**. The shaft may include, for example, an inner diameter of approximately 0.010 inches and an outer diameter of approximately 0.014 inches. The proximal tip of the core wire nests within the handle mechanism **208** that includes a rotatable handle element **209** having a formed central blind bore **210** and a threaded hollow shank **212**. A fixed threaded base **214** having a throughbore **216** receives the proximal portion of the shaft **206** and rotatably engages the handle element to define the actuating mechanism.

Referring now to FIGS. **12** and **13**, the core wire **204** and the shaft **206** extend longitudinally to define the intermediate portion **220** of the guide wire. The filter element **222** is mounted to the intermediate portion and includes an intermediate quad filar spring **224** of approximately 0.002 inch diameter wire that extends approximately three to seven centimeters from the end of the shaft, depending on the application. The respective ends of four wires comprising the quad spring are unwound, straightened, and outwardly biased approximately forty-five degrees from the spring axis at spaced apart radial locations to define a plurality of umbrella shaped filter struts **226**. These struts form the support structure for the filter. As shown in FIGS. **14**, **15**, and **16**, the strut spacing may conveniently take on a variety of configurations depending on the particular application desired. Lashed to the struts is a fine wire mesh **228** of approximately 0.001 inches thick within 40 to 500 micron pores for straining particulate matter from the bloodstream.

Further referring to FIG. **12**, the radial exterior of the distal portion of the core wire **204** carries a bonded housing or pod **230** having an axially open mouth **232** slightly larger in diameter than the diameter of the filter in a closed configuration. The mouth opens into a cavity sufficiently sized to fully enclose the filter during insertion or withdrawal of the guide wire. The pod would also have a rounded inward edge at its proximal opening so as to envelop the filter when retracted and prevent unintentional engagement of a stent or catheter upon withdrawal. In an alternative embodiment, the housing **230** can include a reduced-in-diameter collar **260** radially affixed to the core wire proximate the distal end of the core wire. The pod may be fabricated out of a spring material wound in the opposing direction as the spiral struts to improve the sliding of the two surfaces. Other options include a lubricious plastic such as polyethylene.

FIG. **13***a* illustrates an alternative embodiment of the housing **230** in FIG. **13** in which the housing **230** is formed in a frusto-conical configuration including an oversized-in-diameter mouth opening axially outwardly from the core wire distal end and a reduced-in-diameter collar radially affixed to the core wire proximal of the core wire distal end.

Operation of the second embodiment proceeds in much the same way as that of the first embodiment, with the guide wire **200** first directed through the vasculature, followed by tracking with a treating catheter. Like the first embodiment, the guide wire **200** is advantageously adjustable in the blood vessel independent of the catheter, allowing a variable selected distance between the location of the stenosis and the filter. However, the way in which the filter **222** expands and retracts differs somewhat from the previously described embodiment.

With the handle mechanism **208** in a normally open configuration, the operator turns the rotatable element **209** to incrementally drive the core wire **204** axially with respect to the shaft **206**. The relative axial displacement of the core wire causes the filter housing **230** to become disengaged from the filter struts **226**. Because of the spring biased nature of the filter struts **226**, as the filter exits the housing, the struts expand radially outwardly against the blood vessel wall such that the wire mesh spans the vessel diameter. In its extended state, the filer allows bloodflow to continue through the vessel while dislodged material becomes entrapped in the wire mesh for collection in the cavity.

Once the lesion treatment procedure is complete, and the necessity for filtering has completely diminished, the handle mechanism is actuated to pull the core wire back to its original position. This activity causes the housing mouth to re-engage the filter struts and urge the struts radially inwardly as the housing encloses the filter. With the filter fully retracted, the streamlined guide wire may be easily and safely withdrawn from the body.

Those skilled in the art will appreciate the many benefits and advantages afforded the present invention. Of relative importance is the feature that avoids any additional control wires, beyond the guide wire itself, in order to expand and retract the filter. Not only does this minimize the number of components necessary to practice the invention, but the angioplasty procedure itself is made safer for the patient.

Additionally, the present invention provides the capability of adjusting the distance between the filter and the catheter lesion treatment device in vivo, eliminating the need to withdraw the guide wire or catheter for distance adjustment should the relative spacing be inadequate.

The filter itself, in one embodiment, provides substantial manufacturability benefits by requiring only a single braiding step. Consequently, braiding additional filter layers adding to the device's complexity are eliminated. By minimizing the process steps required to fabricate the filter, costs involved in manufacture are greatly reduced.

Moreover, the method of fabricating filters according to the present invention offers added efficiencies in manufacture due to the production line processing scheme. Employing such a scheme serves to dramatically improve the throughput rate of filters to minimize overall costs.

While the invention has been particularly shown and described with reference to the preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention.

For example, the invention may be used in any intravascular treatment utilizing a guide wire where the possibility of loosening emboli may occur. Although the description herein illustrates angioplasty and stent placement procedures as significant applications, it should be understood that the present invention is in no way limited only to those environments.

What is claimed is:

1. A vascular filter guide wire for directing placement of a catheter with respect to a blood vessel lesion and filtering particulate matter dislodged by treatment of said vessel, said guide wire including:

an elongated flexible core wire being insertable and steerable through a patient's vasculature to a position downstream of said lesion;

a tubular flexible shaft disposed along said core wire;

a collapsible filter being coupled at its distal end to said shaft and including a spring operable to radially extend said filter outwardly within said vasculature in order for said filter to trap particulate matter arising from the treatment of said lesion;

said core wire including a filter housing for confining said filter in a closed configuration;

an actuating mechanism operable to actuate said spring in order to radially extend said filter; and

said filter housing is formed in a frusto-conical configuration and axially disposed on said core wire, said housing including an oversized-in-diameter mouth opening axially outwardly from said wire distal end, and a reduced-in-diameter collar radially fixed to said core wire proximate said distal end.

2. A vascular filter guide wire for directing placement of a catheter with respect to a blood vessel lesion and filtering particulate matter dislodged by treatment of said vessel, said guide wire including:

an elongated flexible core wire being insertable and steerable through a patient's vasculature to a position downstream of said lesion;

a tubular flexible shaft disposed along said core wire;

a collapsible filter being coupled at its distal end to said shaft and including a spring operable to radially extend said filter outwardly within said vasculature in order for said filter to trap particulate matter arising from the treatment of said lesion;

said core wire including a filter housing for confining said filter in a closed configuration;

an actuating mechanism operable to actuate said spring in order to radially extend said filter; and

said spring further including:

a plurality of radially spaced apart support struts defining a cage and interconnected through a woven peripheral mesh; and

a biasing element collapsibly hinged at one end along a common radial path on said shaft to bias said struts radially outwardly in an open state.

3. A vascular filter guide wire according to claim **2** wherein:

said spaced apart struts are disposed radially equidistant.

4. A vascular filter guide wire according to claim **2** wherein:

said spaced apart struts are disposed in a spiral relationship.

5. A vascular filter guide wire according to claim **2** wherein:

said struts are formed of a high elastic material.

6. A vascular filter guide wire according to claim **2** wherein:

said woven mesh comprises a polymeric material.

7. A vascular filter guide wire according to claim **2** wherein:

said woven mesh density is in the range 40 to 500 micrometers.

8. A vascular filter guide wire according to claim **2** wherein:

said biasing element comprises a quad filar spring.

9. A vascular filter guide wire for directing placement of a catheter with respect to a blood vessel lesion and filtering particulate matter dislodged by treatment of said vessel, said guide wire including:

an elongated flexible core wire having a proximal end and a distal end, said elongated flexible core wire being insertable and steerable through a patient's vasculature to a position downstream of said lesion;

a tubular flexible shaft slidably disposed along said core wire, said shaft including a proximal portion and a distal portion disposed proximally of said core wire distal end for placement downstream of said lesion;

a collapsible filter coupled at its proximal end to said distal portion of said shaft and at its distal end to said core wire, said filter operable in response to the relative displacement between said shaft and said core wire to radially extend outwardly within said vasculature and trap particulate matter arising from the treatment of said lesion; and

a deployment/retraction mechanism including:

a base formed with a thread ed passage for confining the proximal portion of said shaft; and

a manually rotatable control element, said control element formed with a threaded hollow shank and mounted to the proximal end of said wire, said control element operable to threadably engage said passage and incrementally urge relative axial displacement between said shaft and said wire to extend and retract said filter.

10. A vascular filter guide wire for directing placement of a catheter with respect to a blood vessel lesion and filtering particulate matter dislodged by treatment of said vessel, said guide wire including:

an elongated flexible core wire having a proximal end and a distal end, said elongated flexible core wire being insertable and steerable through a patient's vasculature to a position downstream of said lesion;

a tubular flexible shaft slidably disposed along said core wire, said shaft including a proximal portion and a distal portion disposed proximally of said core wire distal end for placement down stream of said lesion;

a collapsible filter coupled at its proximal end to said distal portion of said shaft and at its distal end to said core wire, said filter operable in response to the relative displacement between said shaft and said core wire to radially extend outwardly within said vasculature and trap particulate matter arising from the treatment of said lesion, said collapsible filter including a continuous woven mesh having a plurality of longitudinal pleats for straining particulate matter; an d

a cylindrical support cage having a closed distal end and a flared proximal end, said distal end fixed to said core wire, and said proximal end extending axially and mounted to said shaft.

11. A vascular filter guide wire according to claim **10** wherein:

said filter is formed with oppositely disposed cone-shaped ends to define a front half and a back half.

12. A vascular filter guide wire according to claim **11** wherein:

said woven mesh is mounted to said back half.

13. A vascular filter guide wire according to claim **10** wherein:

said woven mesh comprises a material from the group including stainless steel and nickel-titanium alloy.

14. A vascular filter guide wire according to claim **10** wherein:

said wire mesh density is in the range 40 to 500 micrometers.

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